

OPTIONS FOR SAFE AND EFFECTIVE PRESCRIPTION DRUG IMPORTATION

HEARING

BEFORE THE

COMMITTEE ON COMMERCE,
SCIENCE, AND TRANSPORTATION
UNITED STATES SENATE

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

MARCH 11, 2004

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED EIGHTH CONGRESS

SECOND SESSION

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OPTIONS FOR SAFE AND EFFECTIVE PRESCRIPTION DRUG IMPORTATION

THURSDAY, MARCH 11, 2004

U.S. SENATE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Committee met, pursuant to notice, at 10 a.m. in Room SR-253, Russell Senate Office Building, Hon. John McCain, Chairman of the Committee, presiding.

OPENING STATEMENT OF HON. JOHN MCCAIN, U.S. SENATOR FROM ARIZONA

The CHAIRMAN. Good morning. This hearing focuses the Committee's attention once again on drug importation, an issue we last addressed 5 months ago. At the time, the Committee didn't have the benefit of Dr. Mark McClellan's direct input on this very important issue.

Today, Mr. McClellan appears before the Committee in his capacity as the Commissioner of the Food and Drug Administration. He's also the President's nominee to be the Administrator of the Centers for Medicare and Medicaid Services. And until late yesterday, he was the chair of the Task Force on Drug Importation that was recently formed by the Department of Health and Human Services.

Dr. McClellan's impressive credentials and his current roles and responsibilities suggest he is one of the most qualified individuals in the Administration to discuss the question of prescription drug importation from both the economic perspective and from the health and safety standpoint. Indeed, Dr. McClellan's experience makes it all the more puzzling that he has, in the past, declined to testify before this Committee on drug importation, despite the fact that we have invited him repeatedly to do so. Considering Dr. McClellan's professional and educational qualifications and his apparent willingness to discuss prescription drug importation in many, many other public forums, his absence from this Committee's prior importation hearings has been troubling.

The matter of prescription drug importation is a complicated one that requires the input of our Nation's best minds. On the one hand, it's imperative that we provide our citizens with access to affordable prescription drugs. On the other hand, we need to ensure the safety of our prescription drug supply. It's a difficult balance, and I'll be the first to say that the demand for lower prices should not lead us to sacrifice the health and safety of our citizens. That's why any legislation that permits the freer importation of pharma-

ceuticals must contain safeguards that protect American consumers from tainted or counterfeit prescription drugs.

Achieving this balance is also why those who oppose importation must engage in this dialogue to tell us what additional or alternative safety measures they believe will work. Saying, "No, we won't participate in the debate," is unacceptable.

Opponents of importation must come to the table with ideas of how to build an effective importation system that protects both the health and the pocketbooks of American consumers. We're past the point of naysaying. It's now time to engage.

We look forward to engaging Dr. McClellan in this extremely important issue and hearing his ideas on how to establish and maintain a safe importation system. I hope we'll enter today into a constructive discussion about how best to strike a balance between affordable prescription drug prices and a safe domestic and international prescription drug supply.

I thank Dr. McClellan for agreeing to appear this morning, and I look forward to hearing his testimony.

I think Senator Wyden was here next, and then Senator Dorgan and Senator Breaux.

**STATEMENT OF HON. RON WYDEN,
U.S. SENATOR FROM OREGON**

Senator WYDEN. Thank you very much, Mr. Chairman. I appreciate your hearing.

The Administration's position on reimportation has always come down to just one issue. Their position has been, if you allow reimportation, you put seniors and consumers at risk and jeopardize their safety. There is not a single Member of Congress that wants to do that, and I think we're all stipulating to that.

But what is so unfortunate and detrimental to the public interest is, having taken that position, the Administration consistently stonewalls when Congress tries to get them to describe exactly how much it would cost to run a safety program and how that safety program would work.

I want to make it clear to Dr. McClellan and others who are here today, that's the question I'm going to ask him. What is it going to cost? How would such a program work? And I don't think this Committee ought to leave this morning without getting an answer to that particular question. The Administration has gone round and round on the safety issue in the past. We don't get to the bottom of it until they say, "This is what a safety program would cost. This is how it would work," and then the Congress can figure out how to put it in place.

Finally, Senator Snowe and I have introduced, I think, the only bipartisan bill in the Senate, the MEND Act that would focus on cost containment, improving the legislation that was enacted last November. It goes to the reimportation issue in particular, in that we remove the advertising tax deduction from companies who limit the sale of drugs to any country, because wholesalers or pharmacies are selling to Americans at a discount, and it seems to me that at a time when companies can increase sales by very slick consumer direct-to-consumer advertising, it seems to be a reasonable step to say that if you restrict supplies to a country because some-

body is selling it to Americans cheaper, then you ought to lose your advertising deduction here.

I do believe it's the only bipartisan comprehensive cost-containment bill that's introduced in the Senate thus far, and I hope I'll have a chance to work with my colleagues on this Committee on that, as well.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Dorgan?

**STATEMENT OF HON. BYRON L. DORGAN,
U.S. SENATOR FROM NORTH DAKOTA**

Senator DORGAN. Mr. Chairman, thank you very much.

I think there is some misunderstanding, among some at least, that this hearing has something to do with a nomination that has been to sent to the Congress for Dr. McClellan to become the Director of the Center for Medicare and Medicaid. It is not about that. That's not what this hearing is about.

Dr. McClellan has been the head of the FDA, has been requested by the Senate and the House to appear before Committees on—in this circumstance, on this Committee, he has been requested, on two occasions, over a number of months, to appear to discuss with us the very, very aggressive campaign being waged across this country with the issue of reimportation of prescription drugs. That campaign, which—and I have documents on it—that campaign has been a campaign of the type I have never seen before, trying to prevent the American people from accessing safe, FDA-approved prescription drugs from other countries, including Canada. And not only the U.S. Senate, but the U.S. House has requested Dr. McClellan to come and testify. He has refused.

In fact, interestingly enough, the Governors Conference had a forum on this very issue in this room when the Governors were last in town. It was organized by Governor Pawlenty of Minnesota. They asked the FDA to be present. The FDA refused. And the FDA, in fact, sent a representative to another forum on the same day that seemed to fit the philosophical approach of the FDA.

My mission is not to stop or start any nomination, or to block or to enhance nominations. My interest is to make sure that no one in this government decides that they can ignore the Congress when asked to testify, if, in fact, they aspire to hold a position of trust and responsibility. They have to be accountable for what they do. And I'm going to ask questions about the same kind of things Senator Wyden will ask.

I believe, for example, as a representative of a state that is a neighboring adjunct to Canada, that a drugstore in Canada has about the same chain of custody as a drugstore in the United States with respect to prescription drugs. And I think it's perfectly safe for a consumer to access the identical prescription drug—the same pill, put in the same bottle, made by the same company. It is perfectly safe for a consumer to be able to access that prescription drug from a pharmacy in Canada, for example. And yet the FDA has had this mission to try to prevent that from happening in almost every circumstance.

So I appreciate, Mr. Chairman, your holding this hearing. I think it's important that we explore these questions, and I look very much forward to having the witnesses appear.

The CHAIRMAN. Thank you.
Senator Lott?

**STATEMENT OF HON. TRENT LOTT,
U.S. SENATOR FROM MISSISSIPPI**

Senator LOTT. Mr. Chairman, I don't know how to delicately do this, but why are we having this hearing?

The CHAIRMAN. We had asked Dr. McClellan, on two separate occasions, to appear before the Committee on the issue of drug re-importation. Dr. McClellan was unable to do so, and so we've asked him to appear again. And after some back and forth, we are very pleased that Dr. McClellan has agreed to appear before the Committee, and I have thanked him publicly and privately for doing so.

As you know, he's a nominee for a new position. But as Senator Dorgan mentioned, it's not about his nomination for the new position; it's about the issue of importation of drugs, because he'll still be heavily involved in that issue in his new job.

Senator LOTT. Well, let me make just two or three points. First of all, I think that he should testify before this Committee, or other Congressional committees with jurisdiction that he has involvement with, when he is requested to appear. And I don't think this Administration, or any Administration, should refuse to do that. There is a tendency sometimes by various people to say, "No, we don't want to come, so we're not coming." Well, we've got a job to do. We don't do it very well. It's called oversight and investigation.

The CHAIRMAN. Right.

Senator LOTT. And if we can't get the right witnesses before us, we can't do our job. And I'm highly offended when Administration officials have the temerity to say, "No, we're not—thank you very much, we're not coming." So I think he ought to be here. I'm glad he's here.

Having said that, I think he's an outstanding individual. I have not said anything on his nomination publicly. I think he's done a great job at a very difficult agency, the FDA. I have generally considered it, you know, pretty much a lost cause. All of my dealings with FDA have pretty much been unhelpful and unfruitful and negative. And I think he's moved in there and done a pretty good job with a tough agency, number one. And, number two, I don't know why in the world he'd want to go where he's going, because he's got an even tougher job.

But I've been very impressed with him. I remember one time we were having a meeting in one of the Capitol offices, and he was asked to comment, and he commented, and after it was over, I, not knowing who he was, I said, "Who is that? That guy really knows his subject matter." And he's a very brilliant person, and I think he'll make an excellent choice.

I hope we can have this hearing, ask the right questions, move his nomination forward. This is an agency that obviously needs strong leadership. And we dumped even more difficulty on his back last year with the Medicare and prescription drug bill. And CMS needs leadership. So I hope we'll do that.

Having said that, one final point. I have always been hesitant to support importation, or reimportation, of drugs because I was concerned about how it would work. I was concerned, legitimately, I believe, about safety. How do we make sure that it's not a placebo or that it's, you know, something different from what we're told? And I've made that point. But I also have told the pharmaceutical industry that they have a growing problem. The cost of prescription drugs is getting unbearable, and I cannot explain to my mother any longer why she should pay twice or two-thirds more than what they pay in Canada or Mexico for the same drugs. I can't do it anymore.

And I've warned the industry for years, "Fix this problem. Because if you don't, we will, and we're probably going to mess it up." This is still America, and my attitude is, if you want to go across the border or if you want to order, by some other forum, a drug and take the chance of it being not what you're told it is, and cause health problems, my attitude is, go to it. It's kind of like eating a cheeseburger.

[Laughter.]

Senator LOTT. If I want to eat a cheeseburger and gain weight, I ought to have that dang right.

But I am now in a position where I'm switching my position. I cannot any longer defend a position that would say to people, "You can't get drugs from—that are unfairly, in my opinion, cheaper in Canada and Mexico."

So I wanted to be here to make the point, Administration witnesses must appear. Number two, I really hope we can confirm this guy. Number three, when the next vote comes, I'm switching my vote on the importation of drugs.

The CHAIRMAN. Thank you very much, Senator Lott.
Senator Lautenberg?

**STATEMENT OF HON. FRANK R. LAUTENBERG,
U.S. SENATOR FROM NEW JERSEY**

Senator LAUTENBERG. Thanks, Mr. Chairman.

I'd like to second the criticism of the lack of willingness of Dr. McClellan to appear in the past. I had a discussion with him, a chance to meet him, and I think we are—I hope that we're past that reluctance. He is a man who knows a great deal about the subject, and he ought to be more than willing to come here and present it, present his views.

But we are holding this hearing because there's one thing that we should have done on the prescription drug bill last year, something we haven't done, and that is examine Medicare, expand the Medicare to include a prescription drug benefit, and then be able to use the enormous bargaining power by the Federal Government to negotiate price discounts based on volume, not unlike the ability that the VA has to negotiate with the companies. It's outrageous that we should hold the population that large hostage to—I don't want to say created reasons; that suggests something that might not be there, but we have to get to the bottom of this and find out why it is that all of the funds for research and development can be spent here, and yet the profits of these companies are so incredibly high.

All Americans are affected by the high cost of prescription drugs. Look at—nearly 14 million seniors have no insurance at all. That includes prescription drugs. So they pay the full freight. Drug prices increasing 15 percent in 2001—seven straight years, double-digit increases. Seniors, working-class Americans are forced to make impossible choices between the medication that they need, and food and shelter. And, like others here, I'm concerned that the prices can be so much lower, 37 percent lower, in Canada for the same prescription drugs sold here in the States. And we see the same thing in the European countries, and it's not right, and we can't explain it satisfactorily to the citizens of our country why it is that drugs are 30, 40, 50 percent cheaper in Europe and other places.

So what's going on here is that these countries are free riders. They benefit from new drugs, while they leave American consumers to bear the financial burden of developing and testing these drugs.

But reimportation can carry a risk, even if it's limited to Canada, and there are real safety concerns that I hope this Congress and the Administration can work out. So let's not squander another opportunity, as we did last year, on last year's medical bill.

Thanks, Mr. Chairman.

The CHAIRMAN. Senator Snowe?

**STATEMENT OF HON. OLYMPIA J. SNOWE,
U.S. SENATOR FROM MAINE**

Senator SNOWE. Very briefly, Mr. Chairman. First, I'd like to include my entire statement in the record.

I had the opportunity, on Monday, to question Dr. McClellan in his potentially new position as Administrator of CMS, and urged him to appear before this Committee to answer these questions, because I think, obviously, it is critical that we establish a framework for allowing the safe importation of drugs. And if there are concerns regarding safety, then obviously I think that we can take the steps to mitigate those issues.

Clearly, there are many ways within a counterfeiting mechanism to establish safe prescription drugs—they're doing it with pharmacists and wholesalers. And I think that we can take the necessary steps to give this access to affordable medications to all Americans. Importation isn't the problem; it is the solution. So hopefully today, as a result of this hearing, we will be able to establish the mechanisms and the steps necessary to go forward in addressing this issue expeditiously in the Congress.

I know that Dr. McClellan indicated, in response to questions on Monday, that he certainly is—you know, could potentially have reimportation limited to the scope and types of drugs that are imported. So we ought to explore those issues here today. What steps, what resources, what authority is essential in order to make this happen?

I believe we should have a proactive approach to developing this legislation. I think certainly there are avenues and provisions that could make this done, acceptable and easier, and to account for the safety certification required under law. And I know the legislation that you have introduced, Mr. Chairman, with Senator Dorgan,

takes those steps. I think it would fall within the framework of the issues and the answers that were provided by Dr. McClellan on Monday. Those are the issues that we ought to explore so that we can do something that almost two-thirds of the American people favor. One in eight households have already been importing medications from Canada.

So I think that the time has come, not only for Congress, but also for the agencies, to remove the barriers, not tell us, you know, how it can't be done, but to tell us how it can be done so we can get this accomplished on behalf of the American people.

The issue concerning prescription drug coverage was one development that was positive for America's seniors. The other issue is the cost and affordability. We also have an equal obligation to address the cost and affordability. And that's why Senator Wyden and I have introduced our legislation, because that is the other side of the equation that also has to be explored as aggressively as possible. So while we do have the benefit, if we mitigate the value of that benefit because of skyrocketing costs of medication, and we deny the American people the ability to have access to imported medications that I think will offer a measure of competition to prescription drug prices, then I think that we have failed to do our jobs. So hopefully this will be a step forward in the process of getting something done now. Not in the long term; it can be done now. We have done anti-counterfeiting measures very successfully with the \$20 bill; it has been a hallmark of success and creativity and technology. We know we can get this accomplished. So I hope that this hearing will move us forward in addressing this issue.

Thank you, Mr. Chairman.

[The prepared statement of Senator Snowe follows:]

PREPARED STATEMENT OF HON. OLYMPIA J. SNOWE, U.S. SENATOR FROM MAINE

Good morning. I would like to thank Chairman McCain for holding this hearing so we can discuss with Dr. McClellan the critical issue of drug importation. We heard earlier this week from Dr. McClellan in the Finance Committee where we considered his nomination to Administrator of the Centers for Medicare and Medicaid Services. I appreciate Dr. McClellan for being with us here today. Both at the FDA and at CMS, the role of drugs in promoting health is an essential aspect of the job.

Prescription drugs not only save lives but they improve the quality of life for Americans and people throughout the world. Unfortunately for too many Americans, obtaining their medication may be no less an ordeal than their illness.

At the crux of the issue before us is the debate over the safety of the importation of prescription drugs. An *ABC News-Washington Post* poll found that seventy percent of Americans favor the personal importation of prescription drugs, despite the inconveniences they encounter. Seniors take trips which may be uncomfortable and arduous just to purchase affordable medications. Why? Because they too often cannot afford the cost of their medications in the U.S.

Americans pay a far higher cost for their prescription drugs than do citizens in other industrialized nations, where despite comparable wealth, the cost of prescription drugs is a small fraction of that in the U.S. Industry argues this disparity is essential to fund industry research. If the developed world must pay higher prices for drugs to support industry research, this financial burden should be shared more equitably.

We're told that importation can't be done, that it isn't safe. Yet one in eight American households *already* use imported prescription drugs. It's astounding to me that the FDA has devoted so much effort to telling Americans not to trust imported drugs—even from Canada—where Dr. McClellan has cited a safe system is in place. But he says the FDA is unable to assure us of the safety of imported drugs.

Well, I want to work with Dr. McClellan—and those at the FDA—in ensuring that we *can* provide a good assurance of safety. We *can* improve safety. Not just our imported drugs but also domestically. For a few pennies, anti-counterfeiting packaging can be used. We use it on a twenty dollar bill. A lifesaving prescription deserves no less. Drug manufacturers can also track their products using a “pedigree”. This provides tracking of where a drug comes from, and who’s handled it. Using little more than a barcode and an Internet connection, a counterfeit lot of drugs could be identified immediately. We want to see a chain of custody—a “pedigree”—for prescription drugs for imported and domestic drugs.

You would also think the FDA would be working hard to improve safety—both at home and abroad. Prescription drugs are a global commodity. You would think we would have been working together by now—it’s been months since the *Washington Post* series last year first showed us that counterfeiting was occurring—right here in the U.S. But instead the FDA has been working against American consumers in failing to tell us what we *can do* to promote safe importation.

It’s time to work together to find answers. The FDA needs to work domestically with HHS and Customs, *and* internationally to ensure the safety of our prescription drugs. Most of all we need you, Dr. McClellan, and your colleagues to work with us. Drug importation isn’t the problem, but one of a number of solutions to obtaining affordable drugs.

I look forward to exploring this issue today. Thank you again, Mr. Chairman.

The CHAIRMAN. Thank you.
Senator Breaux?

**STATEMENT OF HON. JOHN B. BREAUx,
U.S. SENATOR FROM LOUISIANA**

Senator BREAUx. Thank you, Mr. Chairman.

I’m certainly glad to learn that this hearing has nothing to do with Dr. McClellan’s confirmation. You sure had me fooled.

[Laughter.]

Senator BREAUx. But I’m glad to know that it’s not. I think Dr. McClellan is clearly one of the most exquisitely qualified people that have been nominated for this position since we’ve had the position in existence. This is a person who, unfortunately, graduated from the University of Texas.

But, other than that—

[Laughter.]

Senator BREAUx.—Harvard Kennedy School degree in government, Harvard Medical School cum laude medical degree, a Massachusetts Institute of Technology degree in economics, a person who brings a long history of bipartisan service to this position, serving both in the Clinton Administration as a policy advisor, as well as serving with great distinction as the Commissioner of the Food and Drug Administration. That is a unique set of qualifications to run the Center for Medicare and Medicaid, and CMS. And we are fortunate to have a person of this caliber nominated.

He testified before the Committee that is charged with confirming his nomination, the Finance Committee. We asked questions, we got answers in a bipartisan fashion. Every single member voted for his confirmation, other than two.

He testified, in addition, according to press reports—and I was there, something I didn’t agree with, in particular—said, “Medicare Nominee Backs Drug Imports,” were the headlines in the New York Times following his testimony before the Finance Committee on this very issue that we’re talking about this morning. He said, at that hearing—the report said that he would work with Congress, in a bipartisan fashion, to try and assure the safety of prescription

drugs being imported from Canada, and work on legislation to accomplish that. He said the way to do it is give the FDA more money, more personnel, more power to police the imports, and he was going to work with them. In addition to that, the Secretary of HHS, Secretary Thompson, has called for a study to be done. He's appointed a group to look at how to do it.

Now, people who come before the Congress can't do what the law says they cannot do. The law says you cannot import drugs unless we can prove they're safe. The Clinton Administration said, "We can't do that." This Administration said, "We can't do that." And yet some would say that they would like the person in charge of the program to do what the law says they cannot do, and that is impossible. If he did that, then he couldn't be confirmed, shouldn't be confirmed. He has to go according to what the law says.

One of the reasons—and finally—is I think that we have such an issue on trying to find a solution to the cost of prescription drugs is because of the situation we've found ourselves in since 1965. Seniors don't complain about the high cost of doctors, in particular, or the high cost of hospitalization. Clearly, if you went to Mexico or Canada, you could get a doctor to treat you cheaper than in the United States. Clearly, if you went to Mexico or Canada, you could get a hospital to serve you cheaper than you can in the United States. The seniors don't complain about that. Why? Because they have insurance that covers both doctors and hospitals. And now, for the first time, at the passage and signing of the Medicare bill, seniors in this country will have the same advantages that they have in hospitals and doctors, insurance, because they will have insurance for the first time that will cover the cost of prescription drugs. And I think that will go a very long way to easing the pressure on seniors saying, "We can't afford drugs, we can't afford prescriptions, we've got to go to another country to buy them, even though we don't know and can't guarantee that they're safe."

That is a terribly unfortunate situation for our government to say that we're going to solve your problem by letting you go to another country. That's not the way to solve it, and it's not what this Medicare bill does. It provides insurance, and I think that's the way to solve the problem.

Thank you.

The CHAIRMAN. Senator Hutchison?

**STATEMENT OF HON. KAY BAILEY HUTCHISON,
U.S. SENATOR FROM TEXAS**

Senator HUTCHISON. I thank you, Mr. Chairman.

Mr. Chairman, I appreciate Senator Breaux's acknowledgment of the superior education of Dr. McClellan, and I will just expand on that and say he did learn to read in Texas.

[Laughter.]

Senator HUTCHISON. And he read what the Food, Drug and Cosmetics Act requires the FDA to do, and it reads that it is to ensure the safety and effectiveness of all prescription drugs marketed and sold in the United States. And he took that to be his responsibility, and he has carried out that mission superbly.

I think it is important for us to have a hearing to talk about how we can bring down the cost of drugs. But I think that we are tak-

ing the exact right approach in assuring safety first, and, at the same time, because of the Medicare Reform Act that we have just passed, we are beginning to ease the burden on seniors, who have huge problems with medical bills, by giving them drug benefits and options.

I am very pleased that Dr. McClellan is here. I hope he will have a fair hearing, because he is one of the smartest people I've ever met. I've had conversations with him about his view of medicine and medical research and the preeminence of America, and the importance of keeping the preeminence of America in research and creativity and trying to find the new drugs that will make life better and longer for our citizens. I think he's to be commended for taking on an even tougher job than the one he will be leaving, if he is confirmed, and that is to oversee the dramatic overhaul of the Medicare system that Congress has put forward.

So I want to say that I am pleased that he is going to appear here. I hope he will get a fair shake and that his voice will be heard in a responsible forum. And I think it will be. And I very much hope that we will not rush—or force the rushing—into reimportation of drugs without doing all of the necessary studies that would be required, and studies that would show the effects of reimportation of drugs until we have all of the system in place to assure safety.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

I'd like to welcome two of our colleagues from the House who have joined us who have both been deeply involved in this issue, Congressman Sanders and Congressman Burton. And you both look very old. We usually start with the oldest. I'm not sure—

[Laughter.]

The CHAIRMAN.—I'm not sure who is older, so we'll start with Congressman Burton, who I think is older by time in the House, isn't that right?

Mr. BURTON. Yes, but I'm much younger, Mr. Chairman.

The CHAIRMAN. Thank you. Congressman Burton, welcome to both you and Congressman Sanders, and thank you for taking the time. I would ask you to be as brief as possible, because we have a series of votes on the floor. I'm sure you understand that.

Thank you, Congressman. Chairman Burton, welcome.

**STATEMENT OF HON. DAN BURTON,
U.S. REPRESENTATIVE FROM INDIANA**

Mr. BURTON. Mr. Chairman, first of all let me start off by saying that the House has passed the reimportation bill by large majorities, not once, but twice. And we've done a lot of hearings on this subject.

Every year, well over a million seniors and others go across the border to Canada, or through the Internet, and they purchase their pharmaceuticals, and they save hundreds and thousands of dollars in prescription drug costs. As many as 25 Governors and many mayors across this country are trying to do the same thing for their state and local employees because they have budgetary crises and they know that they can save tens of millions of dollars if they buy their pharmaceutical products from Canada.

The second thing I'd like to say is that several organizations from across the country have shown ways that this could be done safely. There's a lot of technology that's been used and can be used. And I think Olympia Snowe, Senator Snowe, mentioned that. The technology used to stop the counterfeiting of the twenty-dollar bill can be used to make sure that these pharmaceuticals are safe. Nanochips can be used to make sure these pharmaceuticals are safe. And pharmaceuticals have been purchased in a safe way across the borders for some time.

We had four hearings on this subject, and we had Assistant Secretary Hubbard come and testify before our Committee. And we asked him, time and again, to give us any examples of where people have been harmed by the pharmaceutical products they have bought in Canada. And we're talking about well over a million citizens that have done this every year. We asked him, on three separate occasions, at three separate hearings. He could not give us one example, not one, where people were harmed from pharmaceutical products purchased in Canada.

Now, let me talk just a minute about Mr. McClellan. We asked him to appear I don't know how many times before our Committee. Not only would he not appear before the Committee, he would not return our phone calls. Now, I understand he's academically qualified. He's a brilliant man, make no mistake about it. We all know that. And I think he can do a very good job. And I'm not here in any way to criticize his confirmation to this position. But I think it's extremely important that anybody in any Administration in a position of leadership should appear before the Congress of the United States when requested. It's extremely important, because we represent hundreds of thousands and millions of people across this country.

The CHAIRMAN. How many times did you ask?

Mr. BURTON. We asked him many times. I can't tell you how many times. But during the time we were asking him to appear, Mr. Chairman, he gave 18 speeches around the country, some to pharmaceutical groups, like PhRMA. And during those speeches, he talked about the reimportation issue to them, but he wouldn't do it to the Congress of the United States, the people that represent this country. And I think that's unfortunate.

So I'd just like to say today—and I know that time is limited, and I've cut my statement very short—we had hearings on this in the House, we've done extensive research on it in the House, it's passed the House twice, overwhelmingly. Reimportation can be very safe. There's technology that ensures safety. Millions of people have been doing it safely without any problems. The FDA can't find any examples of problems.

And so I'd just like to say that I hope Dr. McClellan, in the future, will comply with requests from Congress to come and testify, because it's important. I think you've stated that, Mr. Chairman.

And, second, I think it's extremely important that the American people have an opportunity to purchase pharmaceuticals at a fair price.

Let me give you one example. My wife had breast cancer. It is an absolute epidemic among women in this country. In Canada, Tamoxifen, the drug of choice, costs up to seven times less than it

does in America. Now, why should an American woman who's suffering from breast cancer, who may die from it, not be able to get pharmaceutical products that will save her life at a price very close to what they do in Canada and Europe? It just isn't fair.

And, with that, Mr. Chairman, let me just say I hope Dr. McClellan will get the message from you and from the House that we would like to work with him, but we hope he testifies, when necessary, in the future.

The CHAIRMAN. Thank you very much, Chairman Burton, and thank you for coming over today.

Congressman Sanders?

**STATEMENT OF HON. BERNARD SANDERS,
U.S. REPRESENTATIVE FROM VERMONT**

Mr. SANDERS. Thank you, Mr. Chairman, for holding this important hearing. And thank you, Senator Dorgan, and all of you who are working so hard to end the disgrace of the American people being forced to pay, by far, the highest prices in the world for prescription drugs.

And I concur with Senator Lott and others, who believe that any member of the Administration, in any party, should come before Congress to defend what he or she is doing. And it is not acceptable, to Mr. Burton or myself or Members of the House, that Commissioner McClellan has not done that. I am glad that is here today.

The crisis—one of the major crises in healthcare today—is the fact that millions of Americans are seeing a deterioration in their health, and, in some cases, are dying because they cannot afford to pay the outrageously high cost of prescription drugs in this country. And the Congress of the United States has a right to know, at a time when, year after year, the pharmaceutical industry is the most profitable industry in America, at a time when the pharmaceutical industry has over 600 well-paid lobbyists descending on Congress, at a time when the pharmaceutical industry has spent hundreds of millions of dollars in the last few years forcing Americans to pay sky-high prices for prescription drugs. They have a right to know why Commissioner McClellan, time after time after time, has stood with the pharmaceutical industry, worked hand-in-glove with them to frighten the American people about purchasing safe and affordable medicine in Canada and in other countries.

Mr. Burton is absolutely right when he says that, in the House, in strong, bipartisan, tripartisan support, we passed legislation that says that prescription drug distributors and pharmacists and individuals—and already in America there are well over a million Americans who are doing this today—have a right to purchase medicine in those countries which are safe and where they can get it at a substantially lower price.

Mr. Chairman, this is a healthcare issue. I would hope that somebody asks Dr. McClellan how many Americans are dying today because they can't afford the medicine they need, and how many will suffer if he and the Administration are successful in cutting the lines for safe and affordable medicine.

I would respectfully disagree with Mr. Breaux, who believes that the problem is solved with the prescription drug bill recently

passed. Consumers Union has reminded us that because the pharmaceutical industry was able to inject, in that bill, language which prohibits the government from negotiating for lower prices, one year after the implementation of that bill in 2007, the average senior will be paying more out of his or her pocket for prescription drugs than they are today.

Now, the good news is that, from what we read briefly in the paper, I think in response to a question from Senator Grassley, Dr. McClellan indicated that he would be willing to work with Congress to develop a safe reimportation program. I would urge the Senators to ask for a great deal of specificity in what that program is about. As somebody who introduced legislation dealing with Canada, what we know is that, given the power of the pharmaceutical industry, they can sabotage any agreement that you come up with, unless you do not put very, very clear language in there addressing such issues as a nondiscrimination provision to ensure that drug manufacturers cannot get around the law by manipulating the supply of prescription drugs. We already know that the major drug companies are trying to hold back drugs from Canada.

So I would hope that you ask Commissioner McClellan, who is now ascending, or wants to ascend, to a very important position, hard questions, and hopefully he will come around and work with us so that Americans can receive world-class medicine at the same prices the rest of the world are paying.

Thank you very much, Senator.

The CHAIRMAN. Thank you very much.

I thank both our colleagues for taking the time and coming over and slumming on this side of the Capitol.

[Laughter.]

The CHAIRMAN. I appreciate it very much. Thank you.

We'd like to welcome Dr. McClellan. Dr. McClellan, thank you for your patience, and thank you for your agreement to testify before this Committee. We'd now like to hear any opening statement that you might have.

Thank you.

**STATEMENT OF DR. MARK B. McCLELLAN, COMMISSIONER OF
FOOD AND DRUGS, U.S. FOOD AND DRUG ADMINISTRATION
(FDA)**

Dr. McCLELLAN. Thank you, Mr. Chairman and Members of the Committee. I appreciate the opportunity to testify regarding the cost of prescription drugs and issues related to proposals to legalize importation of prescription drugs into the United States.

Millions of Americans are rightly worried that today more effective drugs are available than ever before, and there's the hope of even better drugs and cures to come, but they won't benefit, because they can't afford the high costs. It has gotten to the point where millions of Americans feel that they have to choose between safety and effectiveness and affordability of their drugs by skipping needed doses, cutting pills, or purchasing unproven drugs from outside the security of FDA's proven regulatory system.

We're at a critical time. It's a time when, on the one hand, the problems of keeping modern medicine affordable are greater than ever, but, on the other hand, we have major new legislation and

new opportunities to help Americans lead longer and healthier lives. For seniors and persons with disabilities, many of the best new opportunities to lower prices and lower costs and to improve quality of care are the result of the major Medicare legislation, which I hope and expect to start providing assistance with drug costs right away. But we also need to carefully examine proposals on drug importation and many other ideas, to find even more ways to bring modern, safe medical care to Americans at the lowest possible cost.

It's easy to understand why more and more people feel like they have no choice but to purchase unapproved imported drugs. Americans without coverage, who walk into a pharmacy and pay list price are facing much higher prices for brand-name drugs in the United States than in Canada, France, or any other country, for that matter. Americans now pay half of all costs of prescription drugs worldwide, even though we account for a much smaller share of prescription drug use around the world.

For many Americans who are left on their own when it comes to prescription drugs, who don't have good coverage that gives them the benefit of negotiated lower prices, the only alternative to high prices seems to be buying cheap medicines from outside the country.

Drug affordability is a serious problem, and there are many things that we are doing and should be doing about it. But under our laws, FDA has been required, for more than 60 years, to assure that drugs are safe, because Congress concluded that you can't simply assume drugs are safe, and it wrote that into the law. Under our laws, drugs must be demonstrated to be safe and effective to be legal. No assumptions allowed, by law.

Other developed countries have similar laws. And when you walk into a drugstore in Canada that serves Canadians, you can be very confident that you're getting a product that is safe and effective. But that's very different from buying drugs internationally, outside of our regulatory protections, from storefronts or websites that don't serve Canadians, but that are designed to make a profit on Americans. As Health Canada and other foreign regulatory authorities have told us, assuring the safety of drugs for Americans is beyond their responsibilities.

FDA works hard to inspect many legitimate manufacturing facilities selling drugs to Americans through legitimate FDA-regulated channels, including facilities located in the United States and abroad. But we have neither the legal authority, nor the resources, to assure the safety of drugs from outside the Federal and state system of regulating drugs. And we've seen many serious safety problems.

We've released several reports in the past year with our partners in border security at the Bureau of Customs and Border Protection that found numerous imported drugs that were improperly labeled, improperly stored, or, even more worrisome, that were controlled substances or drugs like Accutane that present special risks if they don't have proper physician and pharmacist risk management. We've seen many websites that advertise controlled substances and even more dangerous drugs without a proper prescription, putting patients at risk of misuse and abuse. We've seen websites that pur-

port to provide FDA-approved drugs, or purport to provide Canadian drugs, but do not. We've seen counterfeit drugs. Just recently, we worked to shut down a website that was purporting to sell FDA-approved and European drugs, but was really shipping worthless products from India.

We've tried to work with Canadian authorities so that Americans can be assured of notification in the event that their drugs are recalled in Canada. This happened with some important asthma medicines a few months. But there is still no such system in place.

Now, it would be nice to be able to assure that some of these websites are really safe, but our professional staff and our partners in pharmaceutical regulation know from years of experience that you can't just assume safety. And so it's not surprising that these websites carry legal disclaimers. But FDA can't do that. Legal drugs in this country don't carry buyer-beware disclaimers, because legal drugs must be demonstrated to be safe and effective. Not only that, but the Canadian Internet pharmacies themselves have said that they cannot reliably provide large supplies of safe and effective drugs to cities or states or many other Americans.

On the important subject of drug safety and affordability, I appreciate the views of groups like the AARP, which understand that FDA cannot assure safety under current law, and believe that importation should be legalized only if FDA receives the new authorities and resources it needs to assure safety.

In an effort to move beyond just declaring imported drugs to be legal, without assuring that they're safe, Congress and the Medicare law has directed HHS to answer the right questions about importation. How and under what circumstances can the safety of imported drugs be assured, and what would be the consequences for drug prices and patient health?

We are taking this Congressional mandate very seriously. We recently announced a task force to answer these key questions. The task force will hear from a wide variety of healthcare stakeholders and the general public to come up with conclusions for Congress on these key questions about whether and how importation can be done safely and what its consequences would be.

I believe that when we move past rhetoric to a scientific objective analysis, bipartisan progress is possible, and the public wins. After 9/11 and through the first half of 2002, in response to recognition that the threats to our foods had increased, we worked, in a bipartisan fashion with Congress, to review the evidence on whether there were gaps in the safety and security of our food imports, and how they could be addressed. As a result, Congress, with leadership from its authorizing committees, passed bipartisan legislation that gives us an unprecedented ability to protect our food imports from deliberate or accidental attempts to contaminate them, while still encouraging safe imports.

As a result of this bipartisan legislation, FDA has boosted its food-security activities at the border substantially, with literally hundreds of new inspectors and support staff, supported by hundreds of millions of dollars in new food safety and security funding. And that staff is backed up with new legal authority. For the first time, we are being notified in advance of essentially all commercial food shipments ahead of time to allow us to target our efforts to

the riskiest products before they enter the country. For the highest-risk foods regulated by USDA, meats and poultry, the resources and international authorities go even further. We can have confidence in imported meats because USDA has the authority and ability to trace products reliably to their source, to inspect those plants for compliance with USDA regulations. So thanks to bipartisan action by Congress to find effective ways to assure safety, we have enhanced abilities to take action to prevent the ability of foods to come into this country that are unsafe.

We have nothing like these authorities and resources for assuring that entire new classes of imported drugs are safe, such as drugs that are similar to FDA-approved drugs, while protecting Americans from those who would profit by exploiting any weaknesses in our drug safety and security system.

We are going to be working hard, with help from the public, to answer these questions about whether and how importation could work best, and whether large-scale savings would be possible. But we're not waiting. We will continue to use all the authorities and resources we do have now, under the law, to improve both drug affordability and drug safety.

Looking around the country, there are many better, proven ways to help control drug costs, ways that don't sacrifice safety under current law, ways that have been actually demonstrated to work, ways that can be legally implemented right now. Many states have already taken innovative steps in recent years to help bring drug costs under control while working to deliver higher quality care. And it's clear that there are still many opportunities to deliver lower-cost drug benefits without compromising safety and quality.

For example, at FDA we've made a priority of helping Americans substitute generic drugs for the brand-name equivalent. It's a cost-effective way of achieving 50 to 70 percent savings in drug costs. FDA has stronger, larger programs in place than ever to make sure that generic drugs are just as safe and effective, and we're implementing new regulations and other reforms to make that as soon as legitimate drug patents expire, we have broad generic competition.

As a result of these recent steps by the FDA, generic drug prices in the United States are just about the lowest in the world—on average, 20 percent lower than in Canada for the ten most popular generics, and half as much, on average, as in Italy and Germany for unbranded generics.

Today, generic prescriptions have increased to 55 percent of all prescriptions. But good drug plans that help educate patients and providers about generics can get that share up even higher, to 60 or 65 percent. And today most states are still spending about 7 or 8 percent of their Medicaid budgets for higher-cost brand-name drugs that have low-cost generic alternatives, according to data from CMS.

There are many other proven legal steps that we can take to cut drug costs right now, including disease management and pharmacy programs, and steps to prevent errors and costly medical complications through electronic technologies, like FDA's new requirement for bar codes on medicines. We owe it to patients, today and tomorrow, to make our medical future brighter, healthier, and more af-

fordable than ever. FDA's scientists, doctors, and healthcare experts remain dedicated to this critical public-health goal, while protecting us all from bad medicine.

Thank you for listening to my opening statement. I'd be happy to answer any questions that you all have.

[The prepared statement of Dr. McClellan follows:]

PREPARED STATEMENT OF DR. MARK B. MCCLELLAN, COMMISSIONER OF FOOD AND DRUGS, U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Introduction

Mr. Chairman and Members of the Committee, I am Dr. Mark B. McClellan, Commissioner of Food and Drugs at the U.S. Food and Drug Administration (FDA). I appreciate the opportunity to testify regarding the cost of prescription drugs and the issues relating to proposals to legalize importation of prescription drugs into the United States.

At FDA, our statutory responsibility is to assure the American public that the drug supply is safe, secure, and reliable. For more than 60 years, the Food, Drug, and Cosmetic Act has ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness and preventing complications. In carrying out this responsibility, FDA also works to do all we can under the law to make medicines accessible and helping doctors and patients use them as effectively as possible, through such steps as expanding access to generic medicines, reducing the time and cost of showing that new medicines are safe and effective, and providing up-to-date information for health professionals and patients to obtain the benefits and avoid the risks associated with powerful medicines. That is my primary mission and that is the primary mission of the thousands of dedicated staff, including leading health care experts, doctors, economists and scientists who work tirelessly at FDA in public service for the American people. In this role, I, like many of my predecessors before me, have raised substantial concerns about unapproved, imported pharmaceuticals whose safety and effectiveness cannot be assured because they are outside the legal structure and regulatory resources provided by Congress. I have also taken steps within the law to improve the availability of affordable medicines and reduce drug costs, without compromising safety. In my testimony today I look forward to having the opportunity to engage in a constructive dialogue about the issue of importing prescription drugs as well as discussing steps to provide greater access to more affordable prescription medications.

Reducing Drug Costs

FDA shares with Congress its great concern for senior citizens and other patients who have difficulty paying for prescription drugs. That is why the Administration worked with Congress to enact the new Medicare prescription drug law. And that is why at FDA, I have made it a priority for the Agency medical and scientific experts to establish and expand programs that promote access to innovative treatments to help Americans live healthier lives and assure that Americans have access to medications and treatments that they can afford.

FDA has taken a number of significant steps to provide greater access to affordable prescription medications, including unprecedented steps to lower drug costs by helping to speed the development and approval of low-cost generic drugs after legitimate patents have expired on branded drugs. Generic drugs typically cost 50 to 70 percent less than their brand-name counterparts. On June 18, 2003, FDA published a final rule to improve access to generic drugs and lower prescription drug costs for millions of Americans. These changes will save Americans over \$35 billion in drug costs over the next 10 years, and will also provide billions in savings for the Medicare and Medicaid programs. I was pleased that elements of this rule were codified as part of the Medicare law and that, with FDA's technical assistance, the law added additional mechanisms to enhance generic competition in the marketplace.

In addition, last year the Administration supported and Congress enacted an increase of \$8 million for FDA's generic drug program, the largest infusion of resources into this program ever. This increase in the generic drug budget enables FDA to hire additional expert staff to review generic drug applications more quickly and initiate targeted research to expand the range of generic drugs available to consumers. Improvements in the efficiency of review procedures have led to significant reductions in approval times for generic drugs since 2002, and consequently will

save consumers billions more by generally reducing the time for developing generic drugs and making them available.

The Agency has also taken steps to help improve the development process to help lower the high cost of developing new drugs. In particular, FDA is continuing to improve the methods by which assistance and advice is provided to sponsors regarding what we believe are the best approaches to develop new therapies and maximize the prospects for swift FDA approval. These ongoing efforts are designed to provide sponsors with the best possible information and thus increase the efficiency of the development process. We expect that reforms in drug and biologic manufacturing requirements should help reduce manufacturing costs by 20 percent. FDA has identified several priority disease areas, such as cancer, diabetes and obesity, and new technologies including gene therapy, pharmacogenomics and novel drug delivery systems that are good candidates for efforts to clarify regulatory pathways and clinical endpoints.

FDA is also working to prevent adverse events through new rules that would require bar coding for drugs and better ways to track adverse events automatically with the goal of preventing billions of dollars in unnecessary health care costs each year. FDA's final rule requiring bar coding of drug is estimated to have net economic benefits of approximately \$3.5 billion per year. Avoiding such preventable medical complications will also help reduce health care costs, while enhancing quality and safety. In addition, the Agency is striving to promote electronic prescribing, to improve quality and reduce prescription costs as well.

Importation Of Prescription Drugs

Sixty-five years ago, Congress responded to widespread instances of unsafe drugs by directing FDA to create a system for assuring that Americans have a drug supply they can trust will not harm them. Over forty years ago, Congress required that legal drugs be proven to be effective as well, because modern medicines—when they are produced, distributed, prescribed, and used properly—should not only be safe but also should prevent the many complications and side effects of diseases. More recently, in 1988, Congress enacted the Prescription Drug Marketing Act (PDMA) to establish additional safeguards to prevent substandard, ineffective, or counterfeit drugs from entering the U.S. Under PDMA, it is illegal for anyone other than the drug's original manufacturer to re-import a prescription drug into the U.S. that was manufactured in the U.S. This law was enacted with strong bipartisan support because of high-profile cases of unsafe and ineffective drugs entering the United States in large volumes. In one instance, over 2 million unapproved and potentially unsafe and ineffective Ovulen-21 "birth control" tablets from Panama were distributed throughout the U.S. In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, found its way into the U.S. drug distribution from a foreign source. Over the years, FDA's dedicated professional staff has employed PDMA and other authorities to build a drug safety infrastructure to ensure that Americans enjoy the highest-quality drug supply in the world.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This is evident in the recent significant increase in efforts to introduce counterfeit drugs into the U.S. market. FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990s. Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well-funded and elaborately organized networks. At the same time, inadequately regulated foreign Internet sites have also become portals for unsafe and illegal drugs. For example, FDA recently worked with domestic and international authorities to shut down a website that was advertising "FDA-approved" and safe "European" birth control pills and other drugs, but was actually responsible for importing ineffective, counterfeit drugs. Evidence strongly suggests that the volume of these foreign drug importations is increasing steadily, presenting an increasingly difficult challenge for Agency field personnel at ports-of-entry, mail facilities, and international courier hubs, and our laboratory analysts and border and law enforcement partners.

FDA is doing its best to use its limited international authorities and resources to stop the increasing flow of violative drugs into this country, but the task is daunting. Each day, thousands of individual packages containing prescription drugs are imported illegally into the U.S. FDA's Office of Regulatory Affairs has inspectors who work in the field who perform investigational work pertaining to imported prescription drugs, a job that is not limited to inspections at ports of entry.

Safety Concerns Relating To Importation

FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to prevent against degradation, and there is no assurance that these products were manufactured under current good manufacturing practice standards. When consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.

Patients also are at greater risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some purchasers of drugs from foreign sources may receive genuine product, others may unknowingly buy counterfeit copies that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Furthermore, in the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, the consumer may have little or no recourse either because the operator of the pharmacy often is not known, or the physical location of the seller is unknown or beyond the consumer's reach. FDA has only limited ability to take action against these foreign operators.

The Agency has responded to the challenge of importation by employing a risk-based enforcement strategy to target our existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety and counterfeit drugs. However, this system as it works today is already overwhelmed by the number of incoming packages, and this presents a significant ongoing challenge for the Agency.

Recent spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous or unapproved drugs that pose potentially serious safety problems. In 2003, inspectors found that the majority of the packages examined in these "blitzes" contained illegal, unapproved drugs. Last summer, FDA and CBP conducted blitz examinations on mail shipments at the Miami and New York (JFK) mail facilities in July, and the San Francisco and Carson, California, mail facilities in August. In each location, the agencies examined packages shipped by international mail over a 3-day time span. Of the 1,153 shipments examined, the overwhelming majority (1,019 packages, or 88 percent) contained unapproved drugs. The drugs arrived from many countries. For example, 16 percent entered the U.S. from Canada; 14 percent were from India; 14 percent came from Thailand, and 8 percent were shipped from the Philippines.

A second series of import blitz exams, conducted in November 2003, also revealed potentially dangerous, illegally imported drug shipments. Of the 3,375 products examined, 2,256 or 69 percent were violative. FDA found recalled drugs, drugs requiring special storage conditions and controlled substances. These blitz exams were performed at the Buffalo, Dallas, Chicago and Seattle international mail facilities and, for the first time, the private courier hubs at Memphis and Cincinnati. Canadian parcels appeared most frequently (80 percent of the mail parcels), while 16 percent were from Mexico, and the remaining 4 percent came from Japan, the Netherlands, Taiwan, Thailand and the United Kingdom.

Examples of the potentially hazardous products encountered during the exams include:

- Unapproved drugs such as (1) alti-azathioprine an immunosuppressant drug that can cause severe bone marrow depression and can be associated with an increased risk of infection and cancer development; and (2) human growth hormone, which can have serious side effects if used inappropriately or in excessive doses.

- Controlled substances—FDA and Customs found over 25 different controlled substances were found, including Diazepam; Xanax; Codeine; Valium, Lorazepam, Clonazepam and anabolic steroids.
- Drugs withdrawn from the U.S. market for safety reasons such as Buscapina, which appears to be the drug dipyron, removed from the market in 1977 due to reports of association with agranulocytosis—a sometimes fatal blood disease.
- Improperly packaged drugs shipped loose in sandwich bags, tissue paper or envelopes.
- Animal drugs not approved for human use such as Clenbuterol, a drug approved for the treatment of horses but also known as a substance of abuse in the “body building” community and banned by the International Olympic Committee.
- Potentially recalled drugs—American consumers were sent Serevent Diskus and Flovent Diskus medicines from Canada for the treatment of asthma. Shortly after the blitz, certain lots of the Canadian versions of these drugs were recalled in Canada.
- Drugs requiring risk management and/or restricted distribution programs—For example, Canadian-manufactured isotretinoin, which in the U.S. is subject to a stringent risk management plan, under which prescribers are required to screen, educate and monitor patients to avoid certain serious risks such as birth defects.
- Drugs with inadequate labeling such as those with missing dosage information or labeling that is not in English.

But its not just the FDA that has identified both legal and safety concerns about importation of prescription drugs, so have many other professional regulators, including State pharmacy boards and most recently courts. On November 6, 2003, Federal District Court Judge Claire V. Eagan, U.S. District Court for the Northern District of Oklahoma, issued a decision in *United States v. RX Depot, Inc. and RX of Canada LLC*, granting a preliminary injunction to immediately prevent these defendants who operate business that import prescription drugs from Canada, because such unapproved drugs were a clear violation of the Federal Food Drug and Cosmetic Act. In addition to her unequivocal findings of law, the Judge concluded that these companies could not assure the safety of the drugs they have been importing and, as a result, in violating the law have put Americans at serious risk. The Judge concluded that “unapproved prescription drugs and drugs imported from foreign countries by someone other than the U.S. manufacturer does not have the same assurance of safety and efficacy as drugs regulated by the Food and Drug Administration.” She continues: “Because the drugs are not subject to FDA oversight and are not continuously under the custody of a U.S. manufacturer or authorized distributor, their quality is less predictable than drugs obtained in the United States.”

Recent State Actions

Despite this ruling and the concerns raised by the Agency, recently, several governors and mayors have proposed to create systems whereby their employees and/or constituents could be directed to Canadian pharmacies for purchasing Canadian drugs. FDA has spoken with a number of such officials about our concerns, and many have declined to proceed and have turned to other legal, proven ways to safely reduce drug costs. However, some states and localities, including the State of Minnesota and the State of Wisconsin have proceeded to establish state run websites linking citizens to entities dispensing drugs purportedly from Canada.

Recent research by the state of Minnesota pointed out significant problems related to purchasing non-FDA approved pharmaceuticals from foreign Internet pharmacies. Even Canadian pharmacies that participate in the Canadian Internet Pharmacy Association were observed engaging in problematic practices during a single, voluntary, pre-announced “visit” by Minnesota State officials. Minnesota state health officials noted dozens of safety problems, such as:

- (1) several pharmacies used unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify prescription questions;
- (2) one pharmacy had its pharmacists review 100 new prescriptions or 300 refill prescriptions per hour, a volume so high that it would have been impossible to assure safety;
- (3) one pharmacy failed to label its products, instead it shipped the labels unattached in the same shipping container, even to patients who received multiple medications in one shipment; and

(4) drugs requiring refrigeration were being shipped un-refrigerated with no evidence that the products would remain stable.

At least one of the Canadian pharmacies visited by Minnesota health officials dispensed many drugs that apparently were not even of Canadian origin, and many of the drugs were obtained from prescriptions that had been written and rewritten across multiple Canadian provinces. These types of systematic safety problems, which appear to be a common way of doing business, would generally be clear regulatory violations that would not be tolerated under the comprehensive system of Federal and state regulation of drug safety in the United States.

Drug Counterfeiting

In addition, counterfeiting of prescription drugs is a growing global concern. In fact, counterfeiting of drugs is commonplace in many countries. In the United States, counterfeiting of drugs has been kept to a minimum because of our extensive system of laws, regulations, and enforcement by Federal and state authorities. As a result, Americans have a high degree of confidence in the drugs they obtain from their local pharmacy. In recent years, however, the FDA has seen growing evidence of efforts by increasingly well-organized counterfeiters, backed by increasingly sophisticated technologies and criminal operations, intent on profiting from drug counterfeiting at the expense of American patients.

To respond to this emerging threat, FDA convened a Counterfeit Drug Task Force that received extensive comment and ideas from security experts, Federal and state law enforcement officials, technology developers, manufacturers, wholesalers, retailers, consumer groups, and the general public. Based on these comments, on February 18, 2004, FDA issued a report that contains specific steps that can be taken now and in the future to protect consumers from counterfeit drugs and secure the U.S. drug supply chain.

The report's framework describes how to strengthen our drug safety assurances against modern counterfeit threats through a multilayered strategy that includes modern anti-counterfeiting technologies. Promising developments such as "track and trace" technologies that cannot be faked like a paper drug pedigree, and verification technologies built not only into tamper-resistant drug packaging but also into the drugs themselves will make our job of verifying the legitimacy of drug products much easier. FDA is working to speed the availability of these anti-counterfeiting technologies, but these technologies have not yet been proven, and they are intended to complement and reinforce an underlying system for assuring the safety and effectiveness of prescription drugs.

Thus, anti-counterfeiting technologies hold great promise for strengthening our legal drug distribution system, but to be effective they must be used in conjunction with effective legal authorities.

International Drug Prices

As millions of Americans without good prescription drug coverage experience every day, the "list prices" they face for patented drugs when they walk into a drug store in the United States can be much higher than the price of drugs sold abroad. But these price differences do not result from a comparative advantage in the production of such goods abroad. Foreign "list" prices are lower in part because of price controls in foreign countries. While drug prices in the U.S. can be much lower than "list" for Americans with good drug insurance, in Canada, the Patented Medicine Price Review Board (PMPRB) limits both initial prices and price increases of patented medicines through a variety of "tests." Price controls at the provincial level also constrain prices.

Studies of patented drug prices often ignore how competition in the U.S. today, building on the measures described above to improve access and competition in generic drugs, effectively lowers generic drug prices so that many are far lower than drug prices abroad. Generic drugs comprise over half of all U.S. prescriptions, a much higher percentage than in most other countries. Furthermore, low generic prices are fully compatible with strong incentives for research and development of new drug products, because generics are allowed in the U.S. only after patents expire. The U.S. policy has meant that patent law and competition, not price controls, are the primary mechanism by which to affect incentives for innovation.

Competition in the U.S. has provided U.S. consumers with some of the lowest priced generic drugs in the world. For example, recent studies examined the prices for seven drugs that are the biggest selling chronic-use drugs for which the first U.S. entry of a generic version occurred in the last ten years (alprazolam, clonazepam, enalapril, fluoxetine, lisinopril, metformin, and metoprolol). Five of the seven U.S. generic drugs were found to be significantly cheaper than the generic version of the same drug available in Canada. Five of the same seven generics were

also more expensive in Australia than in the United States, with some prices being many times greater than the comparable U.S. price.

Many countries could do more to encourage innovation in health care by changing the way their dollars are being spent, to get more value for their citizens. First, most countries need more competition when it comes to generic drugs, which should be made available quickly and used more widely and at lower prices as soon as legitimate drug patents expire. Regulation of generics should not restrict prices and choices; it should focus on promoting free and fair generic drug competition, including lower prices for patients that use generic drugs. The bottom line is that it can be possible to redirect billions of dollars in drug spending, through greater use of less expensive generic drugs, permitting greater financial rewards for developing and providing access to valuable new drugs quickly. This approach encourages innovation without spending more money. If the savings from more competitive generic prices and wider use of generic drugs are applied to providing better rewards for innovative new drugs, this approach could reduce the inequities in new drug prices across countries, while improving the global incentives to develop better drugs.

The international community has started making progress toward greater fairness in drug pricing, with the potential to reduce the excessive burden on American consumers, who currently pay about half of all drug costs worldwide. For example, an agreement under TRIPS last year will make very low-cost medicines available to developing countries for urgent public health threats, such as AIDS. In conjunction with this agreement, many developed nations agreed not to “re-import” these low cost medicines, in recognition of the fact that the price of medicines in a country should reflect that country’s ability to pay. The United Kingdom and France are also taking steps toward increasing payments for innovative new medicines. The fact that significant savings are possible in other developed countries from greater use and more competition involving generic drugs means that it is possible to achieve fairer new drug prices worldwide with less burden on American consumers, without other countries having to spend more.

Importation Proposals

At a time when FDA faces more challenges than ever in keeping America’s supply of prescription drugs safe and secure, legislation to liberalize drug importation without providing concomitant enhancements in FDA’s authorities and resources to assure the safety of these imports could seriously compromise the safety and effectiveness of our drug supply. The volume of importation that could result from enactment of these bills could overwhelm our already heavily burdened regulatory system. In general, these bills fail to provide FDA with adequate authority or resources to establish and regulate the major new “legal” channels for incoming foreign drugs—manufactured, distributed, labeled, and handled outside of our regulatory system—or even to ensure their safety. Some of these proposals would even limit FDA’s existing authorities, which are already being stretched. They would impose unprecedented restrictions on FDA’s ability to inspect and test drugs, and FDA’s authority to block the distribution of drugs we think are unsafe.

Today, FDA drug approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. Under section 801 of the FD&C Act, only manufacturers may import drugs into the U.S. The drugs must be produced in FDA inspected facilities. These facilities and the drugs produced in them are currently covered by the U.S. regulatory system, and it is legal to import these drugs. But legislation allowing pharmacies or consumers to import drugs directly from foreign sources would bypass the protections provided by FDA’s drug approval process and by state regulation of firms that dispense drugs within their jurisdictions.

Some drug importation legislation would limit imports to only those drugs that are FDA-approved and made in FDA-inspected facilities, where the legislation states that it is limited to drugs that comply with sections 501 (adulteration), 502 (misbranding) and 505 (marketing approval) of the FD&C Act. However, this approach fails to provide resources, authorities, or the procedural framework necessary for FDA to assure such compliance. As a practical consequence, the Agency would be forced in many instances to rely on visual examinations of incoming drug packages to determine whether a drug is FDA-approved and in compliance with the FD&C Act. A visual inspection, however, is not nearly sufficient to verify whether these drugs are FDA-approved, manufactured in FDA-inspected facilities or in compliance with the adulteration and misbranding provisions of the FD&C Act. This is no substitute for the existing FDA regulatory process, which tracks prescription from the acquisition of active and inactive ingredients to on-site inspection of manufacturing

and distribution facilities, with documentation of appropriate product testing and handling.

Even if a manufacturer has FDA approval for a drug, a version produced for foreign markets usually does not meet all of the requirements of the FDA approval, and is thus considered to be unapproved. Even if a drug bound for a foreign market is produced in the same plant as a similar drug approved for the U.S. market, FDA is not able to track that drug in foreign commerce before it enters the U.S. Consequently, it is difficult for the Agency to determine that a drug appearing at a U.S. border is in fact the one produced in the FDA-inspected plant, pursuant to FDA approval. Clearly, there are many foreign Internet operators, counterfeiters, and others who are already showing they are willing and able to take advantages of weaknesses in our drug security system. Taken together, these practical problems mean that simply declaring that only drugs “equivalent” to FDA-approved drugs are legal to import fails to provide consumers with safety protections, because the declaration is not accompanied by the resources and authorities needed to achieve the intent of the law while protecting the U.S. drug supply.

I want to be clear that our objections to legislative proposals that would create large, legal channels for drugs to enter our drug supply without assurances of safety are based on concerns that they will create substantial drug safety problems without clear, large-scale, long-term benefits. I have particularly raised concerns about legislative proposals that would create such channels by weakening our existing safety protections rather than providing the necessary resources or additional authorities to enable the Agency to assure drug safety and security. Furthermore, our economic experts as well as many others have raised concerns about the limitations of potential longer-term benefits and savings that could be realized from imported drugs. The Congressional Budget Office has estimated that the savings from even broad, multiple-country importation proposals would be smaller than can be obtained through the generic drug reforms that Congress and FDA are in the process of implementing now. Even the Canadian Internet pharmacy operators have said that they cannot provide safe drugs for Americans on a large scale. These are important concerns, but that does not mean—and I have repeatedly said this—that we are opposed to undertaking a thorough effort to determine whether and how importation could be accomplished safely. But this cannot be accomplished by fiat or with a presumption of safety.

Recently, we have been dealing with the first case of BSE infective cow in the United States—a cow that came down from Canada and was diagnosed as having a BSE infection. In response to this public health risk, we have in place a multi-layered safety approach that includes numerous firewalls to protect the U.S. consumer from being exposed to infected product. As a result of these firewalls (which, using our significant authorities for imported food safety, we just recently enhanced further) the risk of getting vCJD is extremely low. Even so, there are many who support continuing to prohibit or ban the importation of beef from Canada and other countries where BSE infections have occurred. Yet, some have argued for legalizing drug importation in a situation where we don’t even have all of these firewalls in place. This is problematic.

Today, in part thanks to laws recently passed by Congress to ensure the safety of imported foods from the threat of a bioterrorist attack, we have specific authorities to protect our imported food supply, including authorities to detain such foods, require importers to register with the FDA, require adequate record-keeping and prior notification of incoming shipments. When it comes to beef, we go further to restrict entry points and USDA inspection facilities as well as employ animal health protections as needed to assure safety. And yet, when it comes to drug importation, we do not have these types of authorities.

Some Members of Congress are working on the difficult challenge of identifying the resources and authorities necessary to assure safety for certain types of imported drugs. This is a much more constructive approach than simply declaring imported drugs to be legal or restricting FDA’s authorities to keep the U.S. drug supply safe. To help determine whether and what specific authorities and resources would provide for the safe importation of drugs, the conference report of the new Medicare law gave the Secretary of Health and Human Services specified requirements for a study of drug importation. Among these requirements, the conference report asked the Secretary to “identify the limitations, including limitations in resources and in current legal authorities, that may inhibit the Secretary’s ability to certify the safety of imported drugs” and to “estimate agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country.”

Medicare Importation Study and Task Force

Last year, when Congress enacted the new Medicare prescription drug law, it recognized these safety issues and included language that required that the Secretary certify the safety of prescription drugs prior to authorizing their importation. At the same time, Congress directed the Department to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that assures safety. The Department is currently working on that analysis and has created an intergovernmental task force to steer this effort to completion by the Congressional deadline later this year.

The taskforce will include representatives from FDA, the Centers for Medicare and Medicaid Services (CMS), Customs and Border Protection (CBP), and the Drug Enforcement Administration (DEA). The taskforce will bring together a wide variety of healthcare stakeholders to discuss the risks, benefits and other key implications of the importation of drugs into the U.S., and to offer recommendations to the Secretary on how to best address this issue in order to advance the public health. The statutory language and the conference report provide detailed, comprehensive requirements for the importation study.

As an integral part of the study process, FDA will open a docket for public comment and will hold a series of meetings to gather information and viewpoints from consumer groups, healthcare professionals, health care purchasers, industry representatives and international trade experts. Based on its experience with past major legislation on safety issues related to foods and drugs, the Agency believes this process affords Congress and the Administration an opportunity to fully address the complex public health, economic and legal questions in order to make appropriate and effective recommendations about importation of prescription drugs and the associated fundamental changes to the Federal Food and Drug Act and in safety resources that may be required.

Conclusion

The standards for drug review and approval in the U.S. are the best in the world, and the safety of our drug supply mirrors these high standards. The employees of FDA constantly strive to maintain these high standards. However, a growing number of Americans are obtaining prescription medications from foreign sources. U.S. consumers often seek out Canadian suppliers, sources that purport to be Canadian, or other foreign sources that they believe to be reliable. While some foreign drug manufacturers submit their products to FDA for approval, the imported drugs arriving through the mail, through private express couriers, or by passengers arriving at ports of entry are often unapproved drugs that may not be subject to any reliable regulatory oversight. FDA cannot assure the safety of drugs purchased from such sources.

The vigilance of FDA and BCBP inspectors is an important tool in detecting imported products that violate the FD&C Act. Given the available resources and competing priorities facing these agencies, however, experience shows that inspectors are unable to visually examine many of the parcels containing prescription drug products that arrive through the mail and private courier services each day. The growing volume of unapproved imported drugs, which often are generated from sales via the Internet, presents a formidable challenge.

FDA firmly believes that we can and should do a much better job of making safe and innovative drugs more affordable in the United States, but to succeed we need to find safe and affordable solutions that, when implemented, do not put consumers at risk. We appreciate and support the bipartisan commitment to making drugs more affordable for seniors and other consumers and are working hard to achieve the goals of safety and affordability. We believe that Americans should not have to settle for less.

As you know, the President has announced my nomination to head the Centers for Medicare and Medicaid Services at this critical time—a time when, on the one hand, the problems of keeping modern medicine affordable are greater than ever, but on the other hand, we have new legislation and new cures in development that give us more opportunities than ever to help Americans lead longer and healthier lives. We all agree more needs to be done to continue to address the high cost of prescription medicines.

But we must be cautious and deliberate as we consider proposals to accomplish this goal. I urge Members to ensure that any changes do not require American citizens to give up the “gold standard” in drug safety that has become a hallmark in this country. FDA’s scientists, doctors, health care experts and regulators must be empowered to protect us from bad medicine. We owe it to patients today and tomorrow to make our medical future brighter, healthier and more affordable than ever.

Thank you for the opportunity to testify. I look forward to responding to any questions you may have.

The CHAIRMAN. Thank you very much, Dr. McClellan.

Time magazine is not known as a particularly right-wing or left-wing outfit. They did a very extensive cover story not long ago. Let me tell you what *Time* magazine said, quote, "While there is no doubt that counterfeit and adulterated medicines, some potentially injurious, possibly even lethal, are sold over the Internet by unscrupulous vendors, a *Time* investigation suggests the FDA's actions against Canadian imports have been part of a concerted campaign to simultaneously discredit its counterpart agency in Canada, provoke fear among American consumers who buy their drugs there, blunt an exploding political movement among local and state governments to begin wholesale drug buys in Canada, and ultimately preserve the inflated prices charged to U.S. consumers and taxpayers."

That's from *Time* magazine. I think it's very interesting. They start out with an article Senator Snowe probably would be interested in about Helen Clark, of Kennebunkport, Maine, who has to go to Canada because she can't afford prescription drugs without it. And I think that many of the seniors in my state who have to go to Mexico, if asked whether they'd rather go without a prescription drug because they can't afford it or go to Mexico and take a chance, I think most of them would rather go to Mexico and take a chance.

So we're talking about the cost of prescription drugs, as well, and the incredible influence of PhRMA, the Pharmaceutical Research and Manufacturers of America. Now, incredibly, to me, in the Medicare prescription drug bill was a provision that required Medicare not to negotiate—prohibited them from negotiating—with a drug company for lower prices. Did you support that provision of the bill?

Dr. McCLELLAN. I didn't negotiate the bill. I have answered questions about what I would do in implementing the bill, and I do think there are a lot of provisions in the bill that let Medicare get drug prices down for seniors, just like people—

The CHAIRMAN. On that—

Dr. McCLELLAN.—who are Federal—

The CHAIRMAN. On that—

Dr. McCLELLAN.—employees today get lower prices because their plans—

The CHAIRMAN. On that—

Dr. McCLELLAN.—negotiate for it.

The CHAIRMAN. On that particular provision of the bill, did you support that particular provision of the legislation?

Dr. McCLELLAN. I support the provisions in the bill to get drug costs down safely, and, in particular, the provisions for pharmacy benefit managers and other steps to be taken—

The CHAIRMAN. Dr. McClellan—

Dr. McCLELLAN.—to get lower prices—

The CHAIRMAN.—I'm asking you a simple question, and I would like a simple—

Dr. McCLELLAN. Well, I—

The CHAIRMAN.—answer.

Dr. McCLELLAN.—support the legislation. I fully want—I want to implement it as——

The CHAIRMAN. Dr. McClellan——

Dr. McCLELLAN.—effectively as possible.

The CHAIRMAN.—I repeat my question, Did you support that provision?

Dr. McCLELLAN. I support—I support the overall legislation, including the provisions in it. A lot of people have said this is not a perfect law, but it's——

The CHAIRMAN. Dr. McClellan——

Dr. McCLELLAN.—one that will——

The CHAIRMAN.—you've come to this Committee after having stiffed us, after having stiffed the House of Representatives. And my first question, which is a very simple question—a very simple, straightforward question—you won't answer. I will ask, finally——

Dr. McCLELLAN. OK.

The CHAIRMAN.—did you support that provision of the bill, yes or no?

Dr. McCLELLAN. I support the Medicare legislation, including that provision.

The CHAIRMAN. Thank you very much.

I think I'll move on to Senator Wyden, because it probably would be better to do so.

Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

Dr. McClellan, I want to know about the costs of getting a safety program in place, because I think the Administration has just been stonewalling this issue. So we're going to get down in the weeds here for——

Dr. McCLELLAN. Yes.

Senator WYDEN.—a minute. As far as I can tell, with respect to safety, you all do testing, you do raids, and you monitor these websites. How much do you spend now at the agency to try to look at these safety questions?

Dr. McCLELLAN. We do not have a large budget at the agency, given the scope of our overall regulatory activities. Our total budgetary support for Congress is on the order of \$1.5 billion. That includes an enormous scope of responsibility.

Senator WYDEN. But on the safety issue, with respect to imports, how much——

Dr. McCLELLAN. Our total——

Senator WYDEN.—do you spend?

Dr. McCLELLAN.—our total border resources and supporting staff is on the order of several hundred million dollars, and that includes doing all of our food safety activities, including—it includes all of our new counter-terrorism activities and international interactions on trade issues, and the like. And there are a lot international issues related to trade. Our staff——

Senator WYDEN. Let's try once more.

Dr. McCLELLAN.—has a huge reach.

Senator WYDEN. How much do you spend on dealing with safety issues with respect to imported drugs? That's raids, testing, monitoring websites. And I'm asking——

Dr. McCLELLAN. Oh, that's a relatively small amount. I mean——

Senator WYDEN. How much do you think?

Dr. McCLELLAN. I would—in the—in a few million dollars.

Senator WYDEN. Thank you.

Dr. McCLELLAN. Because——

Senator WYDEN. Very good. How much do you think, of that few million dollars, is spent just with respect to Canada? Because I think that there is bipartisan interest in working with the agency on making sure that we can monitor safety with Canada. Now, you've said it's only several million dollars overall. What is it, one million, two million?

Dr. McCLELLAN. We don't have a breakdown like that, because our activities, internationally, go to many countries, including drugs that may be shipped through Canada from other——

Senator WYDEN. All right.

Dr. McCLELLAN.—sources and the like.

Senator WYDEN. But it can't be more than several million dollars, because——

Dr. McCLELLAN. Well, because we don't——

Senator WYDEN.—overall——

Dr. McCLELLAN.—have any comprehensive system in place to work on imported drugs from any countries, including Canada. There's no program like that at FDA now.

Senator WYDEN. We're interested in doing it. But——

Dr. McCLELLAN. Yes.

Senator WYDEN.—I have watched the Administration take Congress around the mulberry bush on this safety kind of question. We can't give you the tools you need until you tell us how much it would cost. And you've now told me that, with respect to imports overall, not just Canada, it's several million dollars.

Dr. McCLELLAN. But, if I could, Senator, if you don't mind me expanding on this a little bit.

Senator WYDEN. Absolutely.

Dr. McCLELLAN. We have set up programs to assure the safety of food imports, and, as a result of the bipartisan legislation in 2002, we were given more than \$100 million each year for new resources to assure border security, to get information in on imports coming into the country, to do registration of foreign facilities, to be able to track imported foods that are coming in. We have nothing like that for drugs. When USDA assures the safety of imported meats and poultry, they have even more resources. They have enough money to pay for inspectors——

Senator WYDEN. How much——

Dr. McCLELLAN.—to go into these individual foreign plants.

Senator WYDEN.—how much do you believe it would cost to set in place the kind of safety program that you believe would assure the American people, with respect to pharmaceutical imports? Just take us through, you know, the costs. We've been debating this for years and years, and we've got to have our hands around that number.

Dr. McCLELLAN. OK. It depends on the scope and volume and type of products——

Senator WYDEN. Well, you——

Dr. MCCLELLAN.—that are brought——

Senator WYDEN.—you lay out the kind of scope——

Dr. MCCLELLAN.—into the country.

Senator WYDEN. Then lay out the kind of scope that you think is in the public——

Dr. MCCLELLAN. Well, there have been different ideas proposed in Congress for the scope of——

Senator WYDEN. Give us yours.

Dr. MCCLELLAN. Well, there—we're trying to work with Congress to come up with a bipartisan solution for doing this. Many Members have suggested, for example—I'll give you a for-example—restricting imports to Canada only, doing a larger number of——

Senator WYDEN. Right.

Dr. MCCLELLAN.—countries would be considerably more expensive——

Senator WYDEN. Right.

Dr. MCCLELLAN.—because it would require a much broader range of imports to be tested. And in that case, we would need to set up mechanisms for assuring border safety, for interacting, much as USDA does when they assure the safety of meats and poultry. And I think the kinds of costs that USDA incurs and that FDA incurs for foods might provide some initial guidance as to what that would be. And that is, as I've just been saying, on the order of several hundred million dollars. But, again, the specific details would depend on exactly what kind of import program Congress envisions, you know, which kinds of imports should be legal, which ones aren't worth the cost of trying to import safely because of problems with assuring their safety because they're controlled substances, or drugs that could degrade under improper storage conditions, or drugs that have very narrow safety indices.

Senator WYDEN. So you're prepared to say, then, that the ballpark for a system involving Canadian imports and something that would responsibly address the safety question would cost several hundred million dollars a year.

Dr. MCCLELLAN. But it could be considerably higher or lower than that, depending on the scope of drugs that are brought in. And that's why it's very important to consider the cost of proposals in conjunction with the authorities that are given to the FDA and in conjunction with the scope and volume of drugs that are to be legalized as part of this system. And that's exactly what we're trying to pursue with our task force and the public input that we're getting from Canadian regulators, from everyone involved in the distribution chain, from consumer groups, and from Members of Congress.

Senator WYDEN. Senator Dorgan and I have been concerned, because in 2000 the FDA estimated that it would need something like \$23 million for the first year of implementation for all countries.

Dr. MCCLELLAN. Which bill are you referring to, Senator?

Senator WYDEN. We understand that that was something that was an FDA estimate in the past.

Dr. MCCLELLAN. You'd probably need to be more specific about the FDA estimates. We often provide technical assistance to Congress on bills that Members, like you, are interested in seeing legislated. And so, it would depend a lot on the type of import program

being envisioned. If this was a smaller one, it would perhaps cost less. I'm not sure that implies an FDA endorsement, by the way, of just being a safe approach. I'd need to know which bill you're talking about and what the provisions are. And I'd be happy to get back to you if you want to send us the information on it.

Senator WYDEN. That involves one of the proposals of Senator Dorgan. But what I want to do is make sure you now tell us what you think a program should consist of. You've given us a ballpark, in terms of costs. Now tell us what you think, in your opinion, not the various advisory committees, your opinion of what a program should cost.

Dr. McCLELLAN. Well, I think there are potentially different ways to do this, provided that the safety assurances can be met. I don't have one specific recommendation, because my experience, in working with Congress—

Senator WYDEN. Your choice, Dr. McClellan. Your choice this morning. Yours. How you'd go about doing it.

Dr. McCLELLAN. I don't have one specific proposal. I think to move forward on this issue and get something done for the American public, we need to find a bipartisan approach that has broad support in Congress, and it gives us the safety authorities and the resources that we need to back up the law, and I'm absolutely willing to work with Congress to find the right answer. That's what we did for the Bioterrorism Act to assure the safety of imported foods. We came up with a number there of about \$125 million a year. But that depended on the scope of imports, it depended on the kinds of authorities that were provided the FDA. And we want to be flexible in working with Congress to address these safety concerns.

Senator WYDEN. Well, my time's up, Mr. Chairman.

The CHAIRMAN. Senator, I'll enter into the record the VA savings. The VA filed 108 million prescription drugs that cost it \$2.8 billion, with savings estimated to be in the hundreds of millions of dollars because the Veterans Administration is able to negotiate with the drug companies for lower prices for our veterans. A provision in this law, a living, breathing testimonial, to the political influence of the pharmaceutical companies, prohibits Medicare from doing exactly what the VA has been doing, saving hundreds of millions of dollars. That's what makes us, Dr. McClellan, a little cynical. And I know you're going to tell me about pharmacy benefit managers and all that, who are able to do it. The pharmaceutical companies put it there for a reason, because when, en bloc, Medicare negotiates, they have enormously more leverage than breaking up into smaller negotiating groups. They know it,

I know it, everybody knows it.

Senator SNOWE?

Senator SNOWE. Thank you, Mr. Chairman.

And to follow up on that issue, I agree, I think we ought to restore that negotiating authority for the Secretary. Second, as Senator Wyden and I have introduced in our legislation, compare, you know, what costs negotiated with the private plans will be participating in the prescription drug benefit program, with those that are negotiated by VA and DOD, and offer an incentive within the stabilization fund to use those funds for incentives. Because that's

going to be critically important. I mean, this is the beginning of a huge issue, with respect to how we implement this program.

And so I think this reimportation question, Dr. McClellan, is a dimension of that issue, frankly. It's how we're going to have a proactive, aggressive approach on the part of government to address the problems and overcome the barriers to solving those problems. I believe in solving problems. I want agencies to solve these problems. There shouldn't be barriers, shouldn't be hurdles, there shouldn't be bureaucracies. We've got the law.

And when I hear you saying, today, that the FDA is charged with the fact that prescriptions imported must be safe, the safety of medications, but it doesn't prohibit FDA from making sure that they are safe. I mean, in other words, the FDA can take the steps to make the reimportation of medication safe. So it doesn't prohibit the FDA from doing that, it doesn't prohibit you, in your capacity as commissioner, now moving on, but it doesn't have a prohibition. So we need to know, what can we do to make it safe?

Now, the legislation introduced by Senator Dorgan and joined by all of us here is, you know, for example, looking at wholesalers. Isn't that a way of doing it? Because you've said that the safety programs within Canada have been very good, they've done a very good job of that.

Dr. MCCLELLAN. Right.

Senator SNOWE. That is your testimony. So there are ways in which we can do it.

You mentioned websites. OK, let's get away from websites for a moment. The legislation we're talking about is wholesalers, pharmacists, the people go to a pharmacy in Canada, present a prescription. It's face to face. Or wholesalers, who are required, obviously, to do their own inspections. We have the same drugs that come from the same manufacturers. We can track all that. So why isn't that something that's possible, right here and now?

Dr. MCCLELLAN. Well, that's certainly something we're willing to—

Senator SNOWE. OK.

Dr. MCCLELLAN.—pursue. What I emphasized, Senator—and I know how strongly you feel about this issue; we've had a number of discussions about it already—is that while the FDA does have the authority to declare certain kinds of drugs approved and safe, we're also constrained by the resources and authorities that we have to assure safety. And our laws were not designed to assure the safety of imported drugs. In fact, Congress made it explicitly illegal in the Prescription Drug Marketing Act of 1987, a strong bipartisan measure that was passed because there were unsafe prescriptions coming into the country. And so that's why I emphasized, in my answer to Senator Wyden, that the right way forward is to figure out what specific authorities and resources FDA needs, which would require legislation, which would be a substantial revision to the Food, Drug, and Cosmetic Act, since it would allow an entire new class of drugs that are currently illegal.

Senator SNOWE. So, well, for example, 10 years ago Congress required the FDA to implement a pedigree so that—

Dr. MCCLELLAN. Right.

Senator SNOWE.—to show the pedigree of medications. Is that—

Dr. MCCLELLAN. That's part of—

Senator SNOWE.—fully implemented? Has that been—

Dr. MCCLELLAN. That's part of—

Senator SNOWE.—fully implemented?

Dr. MCCLELLAN.—that same law. It is not fully implemented.

Senator SNOWE. OK.

Dr. MCCLELLAN. We recently did—

Senator SNOWE. Because that would have—

Dr. MCCLELLAN.—a task force report to get to full implementation through some new technologies that are coming online over the next couple of years, but—

Senator SNOWE. But I see that's at a point, though, that could have been done. I realize you weren't there 10 years ago. But the fact is, Congress did mandate it 10 years ago, so you have a chain of custody—

Dr. MCCLELLAN. It—

Senator SNOWE.—in terms of medication. We could track this. I mean, that's the issue here.

Dr. MCCLELLAN. We could. And that's actually a good example. The way that the law was written had some gaps in it, so that there are ways in which drugs without proper pedigrees could enter the system. And that's why it is not possible to implement it completely and effectively, and it's a good example of where some further legislation could potentially close those gaps. And, similarly, for—potentially, for international.

Senator SNOWE. Well, couldn't it—if there are licensed pharmacists and manufacturers, wholesalers, that were implementing this law, participating in the reimportation, could not that make it safer—

Dr. MCCLELLAN. It could—

Senator SNOWE.—if we did that?

Dr. MCCLELLAN.—if we had an ability. We don't have any legal authority now to license foreign wholesalers, or get them to register, to inspect them, or to test their products, or to do anything like that. We do have those kinds of authorities, in some cases, for food, and USDA certainly has them for the riskiest foods, the meat and poultry. So there might be a good model there.

Senator SNOWE. Did the FDA ever submit a request, based on the requirements of making it safer?

Dr. MCCLELLAN. Well—

Senator SNOWE. We've passed this law three times, as I recall, since 1999, you know, so has the FDA ever made a request of additional resources, authority, or anything in that respect, given the intent of Congress which was made emphatically on three different occasions?

Dr. MCCLELLAN. Well, here now, while I'm at FDA, we have. We are working diligently with the task force required under the Medicare bill to come up with a view that reflects input from outside experts and others on exactly how this can be done, and that's something we're spending a lot of time and effort on right now.

Senator SNOWE. Yes.

Dr. McCLELLAN. And we also want to be responsive to any technical assistance you would like on your legislation, as I mentioned at the hearing on Monday.

Senator SNOWE. Right. Well, you know, the reimportation legislation, and law, I should say—the object of it isn't to subvert the prescription drug law that was recently passed; it's to undergird it, it's to reinforce it, to help people have access to more affordable medications, because that is the other side of the coin here—

Dr. McCLELLAN. Right.

Senator SNOWE.—that we're going to have to grapple with.

Dr. McCLELLAN. Right.

Senator SNOWE. And not only for seniors, but for the 44 million uninsured in America that have no insurance coverage and are desperately seeking, you know, medications. And if we're talking about costs of implementing reimportation, talk about the costs of people not being able to use prescriptions.

Dr. McCLELLAN. Yes.

Senator SNOWE. You know, 20 percent of Americans are, you know, rationing their prescriptions because they can't afford them. Think of the cost to America, the costs to the hospitals, you know, to all of the systems, Medicaid, Medicare, everything across the board. So it is a cost that's going to escalate, given the fact that prescription drugs are out of reach for most Americans, and it's an important component of healthcare today.

So we have got to find a way, sooner rather than later, and I think we've got the dimensions of the legislation that will be introduced by Senator Dorgan and many of us.

Thank you.

Dr. McCLELLAN. And we're happy to provide technical assistance with that legislation. We will continue to work hard on the task force. And I would just add, under the law now there are a lot of steps that we can take to lower costs. We've been doing it with generic drugs, something that the pharmaceutical industry is not supportive of, to get those much more widely available. And we're taking other steps, as well. I'm willing to do everything we can, under the law. But, as you know, the law also requires us, at FDA, to assure the safety of legal drugs in the United States right now.

Senator SNOWE. Thank you.

The CHAIRMAN. Senator Dorgan?

Senator DORGAN. Dr. McClellan, the *Time* magazine article that the Chairman read talked about a concerted campaign. My own view of what you have done—pretty much the view of some of my colleagues—you have been aggressive in trying to prevent the reimportation of prescription drugs, including from, and especially from, Canada. And you know, I'm sure, that the current law allows the reimportation from Canada, provided there are two certifications—one, that it is safe; and, second, that it saves money and saves cost.

Dr. McCLELLAN. Right.

Senator DORGAN. So I just wanted to make that point.

Let me ask, Why have you chosen not to testify, when requested repeated by the U.S. House and the U.S. Senate, on these important subjects?

Dr. McCLELLAN. Well, Senator, I am very pleased to be here today to present our agency's view, and I'm trying to be clear about our concerns about safety and hoping that we can find ways to address both safety and affordability.

Senator DORGAN. That's not what I asked you.

Dr. McCLELLAN. Our agency has consistently tried to do that. We have testified—FDA has testified every single time that we've been asked. I've testified before you, as well, as you know, in an appropriations hearing last year, on this very topic, and we tried to work very constructively with an insurer in your state to address some concerns that they had, and I think we've successfully resolved that.

Senator DORGAN. Dr. McClellan, that's not the question I asked you. I asked you why you repeatedly refused to testify in the House and Senate from Committees that requested your testimony.

Dr. McCLELLAN. Well, when Committees have requested our testimony, we have always provided an FDA witness, including our top experts—

Senator DORGAN. I'm asking why—

Dr. McCLELLAN.—and people whose views are the same as mine.

Senator DORGAN. Dr. McClellan, you head the agency. I'm asking why you have refused to testify.

Dr. McCLELLAN. Well, I—

Senator DORGAN. You aspire to a different position in government, and we wonder whether, in that position, you will decide to refuse to testify.

Dr. McCLELLAN. Senator, this has been a very informative confirmation process for me. I've had a lot of opportunities to talk with Members of Congress, who have had nice things to say about many of the things that we've done, and I've also learned some about problems. The concerns about refusing to testify have been raised with me just in the last few weeks.

Senator DORGAN. Oh, I'm sorry—

Dr. McCLELLAN. We've tried very hard to make sure that we've always had a witness at every hearing, and we've always provided the witness requested.

And with Senator McCain, I'm happy to be here now, but I do want to conclude by saying I'm very sorry about the perception that we haven't been responsive. And I want to make sure that the reality is that when I'm asked to testify, and asked particularly to testify, provided we can make some, you know, reasonable accommodations of scheduling issues, I will be there. I'm absolutely committed to doing that, and that's something that I've very much learned—

Senator DORGAN. Dr. McClellan, I'm sorry—

Dr. McCLELLAN.—about in this process.

Senator DORGAN.—that's disingenuous. I mean, the fact is, you have been repeatedly requested to appear, and have not. And your spokesman, by the way—with respect to this appearance, your spokesman, Mr. Pitts, says you believe you're stepping forward today “in order to reverse the trend that puts politics in front of public health.” So I assume that you believe that this process is all politics and has nothing to do with—

Dr. McCLELLAN. Absolutely not.

Senator DORGAN. Well, then would you inform your spokesman about that?

Dr. MCCLELLAN. I certainly will.

Senator DORGAN. I'd appreciate it.

Dr. MCCLELLAN. And I intend to be here when you request. And I appreciate the attention that this process has put on this issue, and I do want to be responsive, going forward.

Senator DORGAN. Let me ask you a question, if I might. You gave a speech in Canada, in Ottawa, Canada. You said this, "Sometimes people have taken this to mean that we, in the United States, don't think the Canadian system is safe. Let me be clear"—quoting you—"when you go into a well-regulated Canadian pharmacy, just like when you go into a well-regulated U.S. pharmacy, you can be very confident you're getting the right treatment, the right guidance, and what you buy is going to be safe and effective."

Dr. MCCLELLAN. Right.

Senator DORGAN. You agree with that?

Dr. MCCLELLAN. I do.

Senator DORGAN. All right. Then let me ask this. If you believe the chain of custody in Canada offers a prescription drug in Canada that is safe and effective, if it comes from an FDA-approved and inspected plant, are there circumstances in which the FDA will support—under current law, because the current allows reimportation from Canada, if you think it is safe—are there circumstances in which you then would certify it as safe and effective for a pharmacist from North Dakota to go to a pharmacist in Winnipeg, Canada, and purchase a prescription drug made in an FDA-approved plant that an FDA-approved drug, and bring it back for resale in North Dakota?

Dr. MCCLELLAN. We don't have any system in place to assure safety under those circumstances. I think, Senator, that would also break Canadian law, because pharmacies in Canada are not allowed to resell drugs to other pharmacies. Only wholesalers in Canada are allowed to sell to pharmacists, and that's how they maintain that chain of custody. Pharmacies don't have any system set up for maintaining—tracking the drugs and doing recalls and things like that.

Senator DORGAN. Well, let me ask the question again. Would you believe it would represent safety for the consumer if a licensed pharmacist in our country purchased this drug, Lipitor, from a licensed pharmacist in Canada? This drug is made at an FDA-approved plant, sold in Winnipeg to a pharmacist in a chain of custody that you apparently believe is safe, and the same is true in this country. The only difference is, it's twice as expensive in the United States. Same pill, put in the same bottle, made by the same company, different price. Nearly \$2 in the United States, \$1 per tablet in Canada.

So my question is very simple. If a licensed U.S. pharmacist purchases this FDA-approved drug from a licensed pharmacist in Canada, is there a safety issue for the consumer in the United States when it is brought back into this country?

Dr. MCCLELLAN. First, that's illegal under Canadian law and U.S. law now. I think it might be possible to design a system and

make the changes in the laws necessary to assure safety in those circumstances that might be——

Senator DORGAN. I'm not asking about——

Dr. MCCLELLAN.—I'd like to explore.

Senator DORGAN. I'm not asking about your interpretation of Canadian law. I'm asking about current U.S. law, which allows re-importation from Canada, provided there's certification that it is safe. I'm asking, under this specific circumstance, would you consider that safe?

Dr. MCCLELLAN. I would need to know more about how exactly the system would work.

Senator DORGAN. What more would you need to know? If a licensed U.S. pharmacist shops from a licensed Canadian pharmacist—both licensed, both in the chain of custody that is nearly identical, according to you and according to the GAO. I don't understand where there's a safety leakage here.

Dr. MCCLELLAN. The reason that the Canadian system is safe is that the chain of custody requirements—requirements in Canada go from manufacturer to distributor to pharmacist. There is no mechanism in place in Canada to assure the safety of the distribution chain between pharmacist to pharmacist. There's not a system set up to track the drugs through that system. If there's a recall, for example, of the Lipitor product, pharmacists are not equipped to contact other pharmacists to carry out the recall effectively. It's those kinds of steps that could potentially be designed in a new legal or regulatory system, and maybe not even with that much cost. So that's certainly something that I'd be willing to explore, but I'd want to make sure that it provides the same kind of safety assurance that are provided under Canadian law now, and under U.S. law now, for legal prescriptions.

Senator DORGAN. It is the simplest construct I can conceive of, and it appears to me it, too, causes problems for you, and I don't understand that. But let me—*Time* magazine mentioned “concerted campaign” That has been my view, incidentally, a concerted campaign by you, leading the FDA in this direction. Let me refer you to a November, 2003, FDA white paper that you published. And this is right smack in the bulls-eye of the kind of campaign that has been waged under your leadership. And it puts out a white paper that says, Canadian drug prices are higher than U.S. generic prices. And you put together a graph that compares U.S. generics with brand-name drugs in Canada.

Dr. MCCLELLAN. And generics in Canada.

Senator DORGAN. And generics, but that's not what this says. That's not what this chart is, incidentally. And so you've compared U.S. generics with brand names in Canada, suggesting somehow there's complete convertibility.

Isn't it true that, of the top ten-selling drugs in the United States, only one has a generic equivalent? Is that not true?

Dr. MCCLELLAN. I think more than one does, and there are certainly generic alternatives. If I might, the reason for putting that information out is that it turns out that many Americans are ordering drugs from Canada, brand-name drugs from Canada, that do have generic alternatives in the United States. And the drugs included in that chart are consumed by millions of Americans. And

the generic versions here are not only much cheaper than the Canadian brand name that you can buy on the Internet, they're also much cheaper than the Canadian generic versions. So this is part of an educational effort to let people know that there are safe and legal channels for both saving money and getting the prescriptions they need.

Senator DORGAN. If this were an advertisement I'd send it to the Federal Trade Commission as deceptive. There's only one that I know of and that's Prilosec, one of the top ten-selling drugs, that have a generic equivalent, and what you've done is, in a campaign, is put together a chart that suggests somehow that Canadian prices are higher than U.S. prices. You know better than that, and I know better than that. You said in your opening statement that in European countries, and it's true in every country in Europe, and also in Canada, you routinely pay lower prices than in the U.S.

Dr. McCLELLAN. For brand-name drugs.

Senator DORGAN. For brand-name drugs, absolutely. And if there's no generic equivalent then that's what people are buying. And incidentally, you know—we have many examples of these prescription drugs, in which my constituents go to Canada, buy a safe drug produced at an FDA-approved plant, bring it back, they take it, they save money, and the question for them is, Why do they have to be told that somehow this is not legal? Matter of fact, why do they have to drive to Canada to get it? Why couldn't their pharmacist not go there to get it?

But one last question, I know my time is expired, Mr. Chairman, if I might. You, Dr. McClellan, will, in the months ahead, I expect, if you are confirmed by the United States Senate, be confronted with the question that I think the Chairman will certainly ask, and many others in the Congress—and I will support him when he asks it, as Senator Snowe said she would—to abolish the provision in current law that prohibits the negotiation of lower prices with the industry. You will, no doubt, in a new and responsible position, be required to be involved in that. And what will your recommendation be? Will you oppose the legislation that would strike that provision of law, or will you be supporting that legislation?

Dr. McCLELLAN. Well, I can't comment on legislation that I haven't seen yet. I can tell you now that my primary and initial intent is going to be to take the law that we have now, the law that's on the books and that can start delivering lower prices and lower drug costs to seniors right away, and do everything possible with that. It's very clear to me, from my discussions, in this Committee and elsewhere, that there will be a lot of Congressional attention—and that's appropriate—on making sure that we're doing all we can to get prices down safely and giving seniors access to innovative medicine. So I'll absolutely be willing to come back and continue to discuss this issue with you as we work on finding the best ways to get low-cost, innovative drugs to America's seniors.

Senator DORGAN. Mr. Chairman, I have some other questions later.

The CHAIRMAN. Senator Lautenberg?

Senator LAUTENBERG. Thank you, Mr. Chairman.

Dr. McClellan, it's interesting to hear you respond to the questions. You certainly have a way with words, as they say. And it's—

I think we're all struggling to get an answer to the question about whether or not you would support a program to get Medicare the opportunity to negotiate directly. And my hearing's good, and I still can't figure out what you said, in terms of—in your response.

If we know that we can guarantee the safety of these products, would you then say—give us a blanket answer that you would absolutely work—go to work, almost as soon as you take office, because this is the major issue, to bring Medicare into negotiations with the drug companies?

Dr. MCCLELLAN. Well, I don't—I'm trying to be clear, and I'm sorry if I'm not being—I don't support that provision right now, because, under the law, there's an alternative approach to get prices down, and that's to have the—

Senator LAUTENBERG. Any of the—

Dr. MCCLELLAN.—to negotiate lower prices. And, according to CBO and others, this is going to lead to a 20, 25 percent savings, and that's as much as could be gotten by the direct Medicare negotiations. So—

Senator LAUTENBERG. But why wouldn't—

Dr. MCCLELLAN.—first I'm concentrating on implementing—

Senator LAUTENBERG. Why—

Dr. MCCLELLAN.—this law effectively.

Senator LAUTENBERG. But the capacity—the ability to negotiate directly is short, simple, and let the forces go in an open market, as we do so many other products in our country. And it's inconceivable for me to listen to what you say and not be able to get an answer that says, well, if everything is in place, will you then support this as a step along the way, as opposed to comparing it to other opportunities. To me, this—we have a dispute here on—in your testimony today, you say these changes would save Americans over \$35 billion a year in—

Dr. MCCLELLAN. Yes.

Senator LAUTENBERG.—\$35 billion in drug costs over the next 10 years. And I'm not sure what exactly the changes are that are recommended. But we have, from Dr. Allen Sager, Boston University School of Public Health, testified, in 2001, before the Commerce Committee, in which he said that reimportation among—can derive American savings, in 2001, if it could have been done, that would be \$30 billion, in a single year, of savings. You say, in your testimony, that changes will save Americans over \$35 billion-plus in the next 10 years.

What do you think the savings would be if we could loosen up the ability of the Medicare to go ahead and negotiate with the companies? Do you have any idea what could be saved?

Dr. MCCLELLAN. Well, I would defer to the experts on that, like the experts at CBO who have concluded that the prices that Medicare could get would probably not be significantly different than the strong incentives to get lower prices in the Medicare legislation now through plans that work with the doctors to get those low prices. So, in fact, we've seen some recent examples in—you know, Senator as, you know, we talked about yesterday, where Medicare has been overpaying for drugs when there is a regulated price system, and there's a lot of lobbying that goes into that because Medicare is such a big part of the market.

So I do want to do everything possible, under the law, to get prices down, but a lot of experts have concluded that this additional step would not lead to additional savings. And, in the meantime, I want to use all the tools we have now to get prices down.

Senator LAUTENBERG. I want to be sure that I understand. Maybe everyone else does——

Dr. MCCLELLAN. Yes.

Senator LAUTENBERG.—but I don't—that the savings that would be derived from Medicare negotiating directly for prices, with the drug companies, would not be significant savings?

Dr. MCCLELLAN. That's what CBO has concluded, yes.

Senator LAUTENBERG. Do you believe that?

Dr. MCCLELLAN. I think—you know, I'm deferring to the experts who have looked at this bill closely, and who have looked at alternatives closely, and had a lot of experience with seeing what happens when Medicare actually does regulate prices, and seeing that they don't always get to be that low because of all the lobbying and input that goes on for, you know, urging higher prices and the like, so——

Senator LAUTENBERG. Why is the Veterans Administration so adept at getting these prices——

Dr. MCCLELLAN. Well, that's a good question. I've talked to some of the people from the VA, and they have a closed medical system. The VA owns their hospitals, they hire their doctors. It's a government-run and government-operated system. And so when they set up a formulary, they can basically tell their doctors and hospitals, "You go on this drug, and you can't get these other drugs." So of course they can negotiate very big discounts.

Medicare is not set up that way, though. Medicare doesn't own the hospitals. It was very important, in the discussion leading up the law, for seniors to have choices so that if they liked a particular drug, they could make sure to get a plan with that drug on it. In the VA system, you don't have those options; it's one set of drugs that are on formulary, and others that aren't covered. And that's what leads to some of their strong negotiating power.

But that's exactly the kind of thing that I think the drug benefit plans are going to do in Medicare, is work with——

Senator LAUTENBERG. Dr. McClellan——

Dr. MCCLELLAN.—doctors and hospitals and——

Senator LAUTENBERG.—you're a wise——

Dr. MCCLELLAN.—get costs down.

Senator LAUTENBERG.—and educated man, enormously so, despite your obvious youth——

[Laughter.]

Senator LAUTENBERG.—which I always resent, but——

[Laughter.]

Senator LAUTENBERG.—the fact of the matter is that if you can come to a conclusion, to express your view, instead of passing the ball over to CBO. You've got to have an opinion. This is going to be such a large part of your responsibility.

Mr. Chairman, if I can have a couple of seconds more. There was a request from my office to challenge the printing and delivery of circulars to Medicare benefits, suggesting that they might have been politically motivated more toward the election campaign than

toward the information and knowledge that we give to the beneficiaries, to the recipients. And GAO came in yesterday with their report and said, well—and I assume that you have seen it, because you and I did discuss it—that says that, on a technical matter, they couldn't adjudge that this was purely a political program. But they point out things that—and you have to read this report.

They say in this, "We point out that HHS materials have notable omissions and other weaknesses. For example, enrollees for the drug discount card program, which is to start June 2004, may be charged an annual fee, and savings from the discount cards may vary." They say, "We do question the prudence and appropriateness of HHS's decision to communicate with Members of Congress and congressional staff by placing an advertisement in Roll Call." Very critical of the information that's put out in that material. Again, they say they couldn't declare that it was purely political, and, thereby, not stop it. But I would urge you to read this, put this in your banks of knowledge, which is considerable, and—so that we can examine this more closely. They actually removed parts of the original circular, because we caught them with their finger in the publicity jar.

And we're lucky to have someone that has your intellect and your education, but, boy, I would hope that you could be more direct in your—

Senator WYDEN. Would my colleague just yield for a unanimous consent request, just for 30 seconds?

Senator LAUTENBERG. Sure.

Senator WYDEN. Mr. Chairman, I would just ask that the Congressional Budget Office letter to me, of March 3, be entered into the record. It does say, Dr. McClellan, that you would get savings, particularly with respect to single-source drugs comprising about 80 percent of the expenditures of the program. It's, in effect, a change in the CBO position of the earlier letter that was sent to Dr. Frist, and I would ask unanimous consent that that letter—making it clear that CBO does believe that there would be savings as a result of giving the Secretary authority to negotiate their position. I'd ask it be made a part of the record.

The CHAIRMAN. Without objection.

[The information referred to follows:]

CONGRESSIONAL BUDGET OFFICE, U.S. CONGRESS
Washington, DC, March 3, 2004

Hon. RON WYDEN,
United States Senate,
Washington, DC.

Dear Senator:

On January 23, 2004, CBO stated in a letter to Majority Leader Frist that striking the "noninterference" provision (section 1860D-11(i) of the Social Security Act, as added by P. L. 108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) would have a negligible effect on Federal spending. This letter responds to your question concerning the potential for savings if that provision were modified to give the Secretary of Health and Human Services authority to negotiate prices for single-source drugs for Medicare beneficiaries.

Most single-source drugs face competition from other drugs that are therapeutic alternatives. CBO believes that there is little, if any, potential savings from negotiations involving those single-source drugs. We expect that risk-bearing private plans will have strong incentives to negotiate price discounts for such drugs and that the

Secretary would not be able to negotiate prices that further reduce Federal spending to a significant degree.

Nevertheless, there is potential for some savings if the Secretary were to have the authority to negotiate prices with manufacturers of single-source drugs that do not face competition from therapeutic alternatives. Private plans offering a prescription drug benefit to Medicare beneficiaries will have less leverage in negotiating discounts for drugs without therapeutic alternatives than they have in price negotiations for drugs that do face such competition. (In that regard, the Medicare plans will be no different than private health plans that offer prescription drug coverage to other populations.)

Under current law, there already are significant pressures that limit the prices that manufacturers charge for drugs—whether those drugs face competition from therapeutic alternatives or not. Those pressures include the prospects that plans will not cover a drug (or will substantially limit the amount they pay for a drug) and that manufacturers will provoke a backlash (potentially including legislation) if they set prices too high. Moreover, the creation of the Medicare drug benefit has given Federal officials greater opportunity and incentive than under prior law to bring pressure on manufacturers—for example, by influencing public opinion and policy makers—if the prices that manufacturers set for single-source drugs that are not subject to competition from therapeutic alternatives are perceived as being too high. Giving the Secretary an additional tool—the authority to negotiate prices with manufacturers of such drugs—would put greater pressure on those manufacturers and could produce some additional savings.

CBO has not estimated the effect on Federal spending of authorizing the Secretary to negotiate prices for single-source drugs. The extent of any savings would depend significantly on the details of legislative language; a proposal that applied to a broader range of drugs could generate no savings or even increase Federal costs. The effect on Federal spending would also depend on how the Secretary would choose to exercise any new authority to negotiate prices.

If you have any questions, we would be happy to answer them.

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Cc: Honorable William H. Frist, M.D.

Majority Leader

Honorable Tom Daschle

Democratic Leader

Honorable Don Nickles

Chairman

Committee on the Budget

Honorable Kent Conrad

Ranking Member

Honorable Charles E. Grassley

Chairman

Committee on Finance

Honorable Max Baucus

Ranking Democratic Member

Honorable Jim Nussle

Committee on the Budget

Honorable John M. Spratt Jr.

Ranking Member

Honorable William “Bill” M. Thomas

Chairman

Committee on Ways and Means

Honorable Charles B. Rangel

Ranking Member

Honorable Joe Barton

Chairman

Committee on Energy and Commerce

Honorable John D. Dingell

Ranking Member

The CHAIRMAN. Senator Breaux?

Senator BREAU. Thank you, Mr. Chairman. And thank you, Dr. McClellan, for your appearance.

Let me be the first to say that the prohibition in the Medicare bill against the government negotiating the price of pharmaceuticals comes from legislation introduced by both Democrats and Republicans over a long period of time. It's been a very consistent position. It doesn't matter whether it's in the bill or not, in this Senator's opinion, because the structure of the Medicare bill is that the government is not, in fact, providing the drugs; we're using a private delivery system; the drug prices will be negotiated through the insurance providers, who will negotiate with the manufacturers to try and get the best price that they can, so they can sell their insurance products at the cheapest possible price. The government is not involved in the delivery of the insurance products.

So whether there's a prohibition or whether it's there or not, in my opinion, doesn't add—make any difference whatsoever. The fact is that the government doesn't negotiate prices. When the government becomes the principal buyer of the product, we're not negotiating, we're setting the prices, what we have done in hospitals and doctors and what we do every year, and it's a huge mistake, it's a huge mess.

So this is a new methodology, and we don't have the government negotiating, because they, in fact, are not the provider. The insurance companies will negotiate with the manufacturers for the best possible price.

It was interesting that we talked about *Time* magazine. I doubt whether *Time* has done the same degree of inspection of imported drugs as FDA and Customs has over the years. I'd like you to comment on the two recent efforts by Customs and the FDA to try and check the drugs that are coming into this country, and what you've found.

According to information we have in July and August, FDA and Customs conducted a series of inspections involving over 1,150 individual shipments coming into Miami and New York and San Francisco and Carson, California, and you found that about 88 percent, or more, of those drugs, randomly seized in four different locations in the United States, in fact, were illegal. They were tainted, they were not properly refrigerated, and they did not, in fact, have the materials that they allege that they were providing in the actual product that was coming into this country.

FDA, in August—in November, rather, of this past year, just now a few months ago, seized 3,375 random samples of products coming into the United States, seizing them again in Buffalo, New York, Dallas, Chicago, Seattle, and also through shipment points in Memphis and Cincinnati, and found that most of them were coming from Canada, about 80 percent, and, of that amount seized, almost 70 percent were also illegal, improperly refrigerated, did not contain the products that, in fact, they were allegedly containing.

Now, I'm not sure how many of these that *Time* magazine did to reach their conclusion, but when Customs did it, and FDA did it, what do these findings tell you about the current system?

Dr. MCCLELLAN. Well, they tell me that there are some safety gaps out there that foreign entities are willing to exploit whenever

they get an opportunity. Senator, we not only saw lots of examples of unsafe and risky drugs coming in; we continue to see websites popping up that purport to be Canadian, but aren't, Internet sites selling controlled substances, and other risky products, not even—you know, they might even be approved products, but they're not dispensed under proper conditions for the safe use of the products. What I hear from my staff every day—they're charged, under the law, with assuring the safety of drugs in the United States—is that there are real safety gaps here, real safety problems.

Senator BREAU. Of the products that some say we can import safely from Canada because they're our friendly neighbors to the north, and a developed society, where is FDA and Customs finding that a large amount of the drugs that, in fact, are coming from Canada actually are coming from? What other countries are involved in using Canada as a transshipment port to bring drugs into the United States?

Dr. MCCLELLAN. In that most recent blitz, we did find examples of drugs that have come from Canada, but were initially from other nations—Mexico, parts of Asia, Europe, and other places.

Senator BREAU. Pakistan, India?

Dr. MCCLELLAN. Some places like that, yes, sir.

Senator BREAU. Let me ask the other question. Suppose you design the best possible system to guarantee that drug products coming in from Canada, for instance, are safe, and we spend millions of dollars to do it. Suppose the drug companies just say, "Look, we're going to figure out what the Canadian consumers need to fill their needs. And if it's 200 pills, we're going to sell Canada 200 pills. We're not going to sell them 500, and import Canadian's price system into this country." What's the current status? What can the Administration do if the manufacturers in this country decide to sell what the consumers in another country need? Can we require them to sell more—

Dr. MCCLELLAN. No, we have no legal authorities to do that. No legal authority to do that. In fact, Canadian Internet pharmacies, themselves, have said that they have concerns about any large-scale importation proposal, because they don't think they could provide cities, states, very large numbers of Americans safely, and there have been cases—for example, the State of Minnesota found a pharmacy that was actually not using Canadian drugs, but was shipping—you know, purporting to provide Canadian drugs, when it was actually shipping drugs from Europe because of these kinds of supply issues.

Senator BREAU. The Medicare bill mandated that the Secretary of HHS conduct a detailed study, and he has created a task force to look at how you could establish this type of safe system. And Senator Wyden talked about how we're going to do it.

Dr. MCCLELLAN. Right.

Senator BREAU. And my understanding is that what we required in the Medicare bill was they would come up with a detailed study to—

Dr. MCCLELLAN. That's right.

Senator BREAU.—find out what would have to be in place.

Dr. MCCLELLAN. That's exactly right.

Senator BREAUX. What is going to happen with that task force? What is——

Dr. MCCLELLAN. That task force——

Senator BREAUX.—being done? And when are we going to——

Dr. MCCLELLAN. That task force is working hard right now. The first public-input meeting for the task force is next week, with consumer groups, including groups like AARP, Consumers Union, others, some of whom support—many of whom support—importation, but also some of whom have wanted to make sure that FDA gets the resources and authorities it needs. That and similar meetings scheduled over the next few weeks, with other components, other people who are going to be affected by this type of proposal, the drug industry, the distribution—the drug distributors, the wholesalers, pharmacists, everyone who's going to need to participate in this effort will be part of coming up with what the best solution or options are for doing this safely and effectively.

Senator BREAUX. And that will be reported to Congress?

Dr. MCCLELLAN. And that will be reported to Congress, as Congress has directed us to do.

Senator BREAUX. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Cantwell?

**STATEMENT OF HON. MARIA CANTWELL,
U.S. SENATOR FROM WASHINGTON**

Senator CANTWELL. Thank you, Mr. Chairman.

Dr. McClellan, I think this is a very important hearing to get your positions on the record as it relates to this bill. And we've heard today that you do, in fact, support that language that was a prohibition on negotiating on pricing. I think, in your testimony, you've elaborated, or started to elaborate a little bit, that you think that there are competitive actions or competitive forces that are going to take place through PBMs and other——

Dr. MCCLELLAN. Yes.

Senator CANTWELL.—vehicles, is that right? Is that——

Dr. MCCLELLAN. That's right. I've had the opportunity to talk with experts from—actually, the VA relies on their own PBM-type system to get their savings. The Federal Employee Benefits Plan, the insurance that I have and you have, relies on PBMs to get prices that are significantly lower than list prices. And there are good models there that I think will be even more effective in the Medicare population, because it's so large. Because millions of beneficiaries who use drugs a lot will be able to band together and demand lower prices, something they can't do today, when they individually walk into a drugstore off the street.

Senator CANTWELL. Well, are you aware, Dr. McClellan, that there is an outcry about PBMs being the middle manager and not passing rebates on to consumers, that, in fact, for free markets to work, and work effectively, with competition, that there has to be transparency, and that the U.S. Government and several states and attorney generals throughout the country are now bringing lawsuits against PBMs?

Dr. MCCLELLAN. And in order to ensure transparency in the Medicare bill, we will build off those kinds of efforts to enforce

transparency. Just as a for example, in the drug card that Medicare is putting together, and will be making available to seniors beginning just in a couple of months, there will be transparency on the final prices that Medicare beneficiaries are going to face. They'll be able to compare what they care most about, what are they actually going to be paying for the drug, you know, not what the rebate is that some manufacturer gets or some health plan gets—what is the bottom line price that they have to pay. So they're going to have much more power—

Senator CANTWELL. Maybe—

Dr. MCCLELLAN.—to find a card. And the only PBMs that are going to work are the ones that are going to give them lower prices.

Senator CANTWELL. Well, I find that hard to believe, because we're already seeing articles that basically are causing my consumers a lot of heartache—months ahead of Medicare prescription drug discounts, basically talking about these PBMs, who are under investigation, and how they have already—you know, people from the Department of Justice investigating MEDCO and others for their practices, and yet these are the very people that are proposing these discount cards.

And so I need to ask you a couple of specific questions, because we've proposed legislation, and I want to make sure I understand, before I support your nomination, where you stand on these. Do you think that pharmaceutical companies should own a pharmacy benefit manager, or do you think we should pass legislation to prohibit that?

Dr. MCCLELLAN. I have not looked at your specific legislation on this issue, but I'd be glad to. And if I'm confirmed, I'm certainly going to work to find ways to make sure that Medicare beneficiaries get transparency, they get to know where the lowest—where the prices—what the prices they're actually going to pay are, and they'll get the lowest prices. And—

Senator CANTWELL. Do you—

Dr. MCCLELLAN.—the Inspector General, other legal authorities that are involved in some of those cases, are the same ones that'll be working with the Medicare program to help enforce the law on getting lower prices to seniors.

Senator CANTWELL. Do you not know, today, whether you believe that a pharmaceutical company should also own a middleman—a pharmacy benefit manager—

Dr. MCCLELLAN. Well, it certainly—I think that's legal under the law now. In general PBMs—

Senator CANTWELL. Do you think it should be legal under the law?

Dr. MCCLELLAN. I think that the law should make sure that seniors get transparency about the final prices that they're paying, and they can see very clearly what they're getting on their drug cards and in their drug benefits. It's final prices that matter. Not rebates, not all this complexity. The law needs to focus on informing beneficiaries about where they can get the most help with their drugs costs.

Senator CANTWELL. That's not the law we have on the books today, and I don't see you advocating for it, either.

Dr. McCLELLAN. Well, I—Senator, I would be very happy to work with your office on any specific concerns you have about making sure that Medicare beneficiaries know what they're paying for their drugs, they know that they're getting a good deal when they sign up for a drug card or a drug benefit. That's absolutely my goal, if I'm confirmed.

Senator CANTWELL. I want to be clear, because it's pretty simple. If you're the middleman, and you're also owned by the parent company, you're negotiating with yourself. So if you negotiate a 30-percent discount for, say the Federal employees, and you pocket it, you're just pocketing it to yourself. Or if you only pass on 10 percent of the discount to the Federal employees, again, you're pocketing—so we don't have transparency. And so I'm—I guess I'm amazed that one of the biggest debates that we have, and I heard from my constituents, is, how are we going to control costs?

Dr. McCLELLAN. Yes.

Senator CANTWELL. When they find out that there was language in the bill prohibiting that cost debate from happening, and now you're saying it's going to happen in the free market, and we have case after case where these middlemen aren't passing on the costs—I mean, the U.S. Government versus MEDCO, destroying and increasing drug costs; Alameda County versus MEDCO, anti-competitive pricing; AFSCME versus Advanced PCS, inflated drug pricings in California and keeping rebates secret; North Jackson Pharmacists are taking suit against these PBMs, anti-competitive practices against small pharmacies, artificially fixing prices. Another case, a West Virginia case, keeps rebates from drug companies that should have been passed on. This is what's going on in America, and you don't even know whether—you don't understand the debate or what legislation—

So I want to ask you an additional question, too, because I know my time is—

The CHAIRMAN. Go ahead. Go ahead.

Senator CANTWELL.—probably running out.

But do you think that these collusive pricing activities ought to be able to be investigated by the Attorney General of our country, and that the documentation on these pricing—the pricing and rebates ought to be passed on, at least in a confidential form, to the Attorney General of our country?

Dr. McCLELLAN. I absolutely think any collusive behavior should be investigated. That's illegal under the law, and that's why, in many of the cases that you just mentioned, it's the U.S. Government bringing suit. And it's going to be the same U.S. Government bringing suit on behalf of Medicare beneficiaries if there are any collusive behaviors taking place that are cheating them out of money.

But it's also why—I want to go back to see if I can make clear my point about the way that I think beneficiaries should get information. I don't think it's of any use to beneficiaries to know whether the rebate's 10 percent or 30 percent or whatever. What beneficiaries care about is what their drug actually costs. And if a drug company is in collusion with a PBM, and they're sending all the money back to the drug company, then that drug price that seniors are going to pay is going to be higher. And that's why I want sen-

iors to know what the actual price is. There hasn't been enough transparency in this market, and that's why it should focus on the bottom line for seniors. What price are they actually going to pay? And if I'm confirmed, I'm going to make sure that information gets out to seniors with the drug cards and with the further steps that we take, so they'll know exactly what they're getting——

Senator CANTWELL. Well——

Dr. MCCLELLAN.—and that a plan that sucks up all the money, through collusion or legal steps or whatever, is not going to be one that they'll choose.

Senator CANTWELL. I disagree with your characterization. I think the public wants to know if somebody used their leverage, as a big market, as a consumer group, to get the 30 percent discount and didn't pass it on to them. I guarantee you, consumers want to know that.

Dr. MCCLELLAN. And——

Senator CANTWELL. And I want to know, as—in your position, do you support legislation making these drug companies and pharmaceutical benefit managers disclose those discounts?

Dr. MCCLELLAN. The bill does include provisions that let the Medicare program know about what is being done with the discounts that are negotiated—whether they're being passed on, whether they're translated into actual benefits for beneficiaries. That, plus knowing about final prices, is a good opportunity, under current law, to make sure beneficiaries are getting lower prices, and that's going to be backed up by the full force of the government against any collusive behaviors.

Senator CANTWELL. Well, Mr. Chairman, I know my time is expired, but maybe on the next round we can talk about exactly what the bill does say, because it does not give that authority.

So thank you.

The CHAIRMAN. Just a follow-up on Senator Cantwell's conversation with you. She believes that the bill does not give the authority. You believe that it does?

Dr. MCCLELLAN. I believe that the bill provides a mechanism for seniors to get much lower prices on their drugs. According to the estimates, close to 20 percent lower prices on brand names, 50 percent lower——

The CHAIRMAN. Dr. McClellan——

Dr. MCCLELLAN.—on generics.

The CHAIRMAN.—you know, these are simple questions.

Dr. MCCLELLAN. And I'm sorry if I'm not being direct. I——

The CHAIRMAN. The question is——

Dr. MCCLELLAN.—certainly want to be.

The CHAIRMAN. Senator Cantwell says that the bill does not give the authority, and you are saying that it does. Now, do you disagree with Senator Cantwell?

Dr. MCCLELLAN. I certainly don't want to disagree with Senator CANTWELL. My understanding of the legislation is that drug benefit providers are required to pass on information about what they're doing with their rebates. I also know that when regulations to implement the drug benefit are proposed, and they're going to be proposed soon, and I'd like to—you know, if I'm confirmed, I'll get over there and get them out soon—there will be a lot of opportunity for

discussing exactly how this transparency would work, and exactly what steps can be taken to effectively address the important concerns that Senator Cantwell has raised. And I——

The CHAIRMAN. It's not a matter of concerns——

Dr. MCCLELLAN.—would be——

The CHAIRMAN.—it's a question of whether the authority is in the law or not. But, Dr. McClellan, you know that probably the major reason why this legislation was passed was because of the support of AARP. AARP views legalizing importation for individuals from Canada as a required issue of top interest and concerns to our members and the American public. How long have you been concerned about this issue of reimportation?

Dr. MCCLELLAN. I've been concerned about it for as long as I've been in this job. It's something that——

The CHAIRMAN. Which is——

Dr. MCCLELLAN.—that I heard since——

The CHAIRMAN.—which is how long?

Dr. MCCLELLAN. Since November of 2002.

The CHAIRMAN. And in this period of time, yet you have not yet formulated a proposal of your own to address this issue?

Dr. MCCLELLAN. Well, we have worked with Congress, we are working, as directed by Congress, through the task force to come up with a——

The CHAIRMAN. Again, a simple question, Dr. McClellan. Have you formulated——

Dr. MCCLELLAN. I don't have my own specific proposal on this now.

The CHAIRMAN. Thank you. Thank you.

Also, the AARP has stated publicly that they believe that the provision prohibiting negotiations should be repealed. According to a 2001 Inspector General's report from the Department of Health and Human Services, quote, "The average prices that Medicare carriers currently use to establish reimbursement amounts bear little or no resemblance to actual wholesale prices that are available to physicians, suppliers, and other large government purchasers. But every time the agency has sought authority to negotiate with drug companies, Congress has blocked them."

I feel very strongly, Doctor, that, particularly with the concerns that have already been raised about PBMs, to rely on them to negotiate for lower prices is not going to get it.

I would hope that since you have been involved in this issue of reimportation, not just from Canada, but European countries and other countries, that you would come up with a proposal. We rely on the Administration and people like you to give us proposals so that we can examine them. We almost never have a piece of legislation seriously considered by the Congress unless we have a legislative proposal, or at least principles, from the Administration. I think it's time that the Administration came up with a proposal so that we can make these importation of drugs both safe and available, since, again, as you and I have discussed several times, we're not talking about an academic situation. We're talking about seniors who are going to bed tonight making a decision whether to pay for a prescription drug or to eat. And I would argue that, since you have been in this job for several years, you will continue in the

same line of work, that you almost have an obligation to these seniors to come up with a proposal of your own so that we can make their prescription drugs more affordable. I hope you will do that, Dr. McClellan. If you want to respond, I'd be glad to—before I turn to Senator Wyden.

Dr. MCCLELLAN. No, go right—I don't want take time away—

The CHAIRMAN. Thank you.

Senator Wyden? And let's try to make it brief. Dr. McClellan has been with us for quite awhile.

Senator WYDEN. Dr. McClellan, when can the Congress expect to get the recommendations from the task force on reimportation?

Dr. MCCLELLAN. The Congressional direction was to do a comprehensive study, and they gave us 1 year to complete that. I believe the Secretary said that he wants to try to move up that date. I'm firmly committed to moving this along as quickly as possible, as well.

Senator WYDEN. So, again, when can you expect we'll get it? I mean, I think—as you look through all this, it's very convenient that if you take the maximum amount of time, the Congress will get it after the election. Don't you think 6 months would be sufficient? Because then people—

Dr. MCCLELLAN. We could certainly—

Senator WYDEN.—then people would have it well before the election, would actually be able to consider their views on that at that time.

Dr. MCCLELLAN. I'd certainly like to get it done sooner. The Secretary firmly committed to that in his testimony yesterday, maybe getting it done by summer. I would also add that while the task force is continuing its activities, we will continue to be able to provide technical assistance to Members of Congress. I know there are many in Congress who do want to move forward with legislation in a timely way, and we will provide assistance for those efforts. You all mentioned legislation that you're introducing. I know Chairman Gregg, in our authorizing committee, the Health Committee, is also interested in finding a safe and effective and timely way to do this, with bipartisan support. And while our task force is ongoing, we certainly want to support the legislative efforts, as well.

Senator WYDEN. I think it's very unfortunate that after 2 hours of discussing this topic, you still haven't told us your preference with respect to how this be put in place. And I've got a couple of more questions. I'd like to know, for example, what technologies you're going to need and—other than bar-coding. I mean—

Dr. MCCLELLAN. Yes.

Senator WYDEN.—there may be some other kinds of tools that you've got—

Dr. MCCLELLAN. I'd be happy to stay and talk with you about that for a little while if you want.

Senator WYDEN. But you've got an opportunity to lead on this issue; and, instead, what you're doing is passing the buck. And you have the opportunity to do that, because Congress did say do it after the election. I think it's unfortunate that you're doing it. I know how talented you are. You and I have worked on these issues—

Dr. McCLELLAN. Yes.

Senator WYDEN.—for a long time. And I think the fact that you're sending this off to a commission and saying, "Let's let another 6, 7 months," who knows how long go by—probably after the election. I don't think that's in the public interest. You've got the expertise. Give us the information about your preference with respect to what it's going to cost, and the nuts and bolts of running the program.

And my last question for you is essentially this. My colleagues have talked about a variety of issues here today, particularly changing the negotiating provision. I've entered into the record the CBO letter, making it clear that there are some savings, particularly with respect to single-source drugs. My question to you is—and I ask this as somebody who voted for the bill—I voted for the bill and still have the welts on my back to show for it. I think there are improvements that can be made.

In your view, how would it undermine the structure of the bill to make the two changes that my colleagues are talking about today, and that Senator Snowe and I have proposed? The two changes, of course, are making it possible to reimport drugs safely, and to give the Secretary negotiating authority. I want to hear your views. How do you believe it would undermine the bill to make those two changes, which go right to the heart of making it possible to better contain costs?

Dr. McCLELLAN. Well, Senator, my concerns about importation, as I've tried to make very clear today, are about finding a way to do it safely. And if the safety concerns can be addressed, I think you'd have the full support of the very dedicated FDA staff that's out there enforcing the law to make sure that the American drug supply is safe, day in and day out, with more complex and more sophisticated threats to the safety and security of our drug supply than ever before. And that's what our task force is about. And I agree with you, we should try to do it as quickly as possible—

Senator WYDEN. Would it—

Dr. McCLELLAN.—and work with you.

Senator WYDEN.—undermine the bill to make the two changes that have been discussed this morning?

Dr. McCLELLAN. Well, I think that importation is an issue that doesn't need to be coupled to the Medicare bill. I mean, importation is an issue that we should be, as we are today, thanks to Chairman McCain, discussing, frankly and explicitly, about the best way to move forward on—I'm very appreciative of the full support from this Committee to addressing the safety concerns and giving the FDA the new legal authorities and resources that we'd need to do it safely. That's not something that I think is tied directly to the Medicare legislation. Is that—does that answer your question about part of—

Senator WYDEN. I'm just asking a straightforward question.

Dr. McCLELLAN. Yes.

Senator WYDEN. We want to make two changes, the reimportation position, and the Secretary's negotiating—

Dr. McCLELLAN. Yes. I don't think—

Senator WYDEN.—authority. As somebody who voted for the bill, I want to know, in your opinion, if you make those two changes

does it undermine the bill? Does it gut the bill? Does it throw the bill——

Dr. MCCLELLAN. I don't think importation, done safely and effectively, has any direct——

Senator WYDEN. All right. How about——

Dr. MCCLELLAN.—impact on the Medicare bill.

Senator WYDEN.—how about the negotiating authority——

Dr. MCCLELLAN. The negotiating authority would be a fundamental change in the Medicare legislation itself, since the way that the legislation——

Senator WYDEN. Would it undermine the bill? The question is—of course it's a fundamental change; it's giving the Secretary some bargaining power—would it undermine the bill? I don't think it would. I believe in using private marketplace forces. That was one of the reasons I voted for the bill.

Dr. MCCLELLAN. Yes.

Senator WYDEN. I think giving the Secretary an additional tool, as the Congressional Budget Office has now said, provides another way to generate savings. I want you to tell me, this morning, in your opinion, giving the Secretary that negotiating authority, would it undermine the bill?

Dr. MCCLELLAN. I think, based on everything I've seen so far, it would not add much to the ability of the plans to get lower——

Senator WYDEN. Would it undermine the bill?

Dr. MCCLELLAN.—prices, but I'd be happy to talk with you——

Senator WYDEN. Would it undermine——

Dr. MCCLELLAN.—further about ways to do it to where it might not undermine the bill. I don't see a compelling need for it right now to get lower prices for seniors and lower drugs costs, because, as CBO and others have said, this is a way to get costs down, but I do want to talk with you further about the issues related to single-source drugs and whether that can be a substantial source of savings without putting patients at risk. I'm happy to discuss that with you further.

Senator WYDEN. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Dorgan?

Senator DORGAN. Mr. Chairman.

Dr. McClellan, the reason you are here this morning is, this Committee had asked you to testify, the letters from three—six Members, rather—seven Members of the U.S. House to the Senate Finance Committee saying they had asked you to testify; you refused. And so you're here today. And you indicate that you want to find a way to work with us to do this safely, but there's no evidence that you've been interested in that at all.

In fact, a letter you received February 10 from seven Members of the U.S. House, Republicans and Democrats, said the following—these are seven bipartisan Members of the U.S. Congress—"It's disheartening, instead of working with the Congress to find common solutions for lowering drug prices and ensuring the safety of the drug supply, the FDA is spending its resources to produce inflammatory, unscientific attacks on legislation that stands to benefit all Americans."

So this is a bipartisan group of Members of the U.S. House that sends you a letter. I mean, look, you need to understand that what

you have done has not sent any signals to anyone that you want to work with us. In fact, it has been exactly the opposite. These folks think you have waged an inflammatory, unscientific attack on this idea.

So that's why you're here. And let me ask you a question about—you say you want to help now, help us find a way to do this safely. You know that Europe does this, something called parallel trading. You're in France and want to buy a prescription drug from Spain, no problem. You're in Italy and want to prescription drug from Germany, no problem. Apparently no safety issues. So, in Europe, they've found a way to do that which you oppose. If you're looking to really help us find a way to do this, is there an instructive example with respect to parallel trading in Europe and——

Dr. McCLELLAN. I do think that's quite instructive. I've actually had this discussion with some of the Members of Congress who support importation. For example, Congress Emerson, Jo Ann Emerson, has talked to a number of European pharmaceutical companies and others involved in parallel trade over there, and has actually suggested some participants in the upcoming meeting that we're going to have with the task force on how other regulatory agencies around the world have dealt with parallel importation.

There are some differences in Europe. One is that there is a European Union government structure, so that when they want to apply consistent regulatory methods, there's this over-arching body that can help make it happen across countries, and address safety. In addition, they are having some concerns over there about the safety of parallel importation. The European Union, as you know, is expanding to include a number of Eastern European countries, some of whom have significant rates of counterfeit drugs and other safety problems.

So I absolutely think there's a lot to learn from that kind of effort, and we intend to incorporate that in our task force work.

Senator DORGAN. Well, Dr. McClellan, we've actually had someone sit in the chair that you're now sitting in that comes from the European Union, and who's involved in parallel trading, and his testimony would not emphasize that they have some concerns; his testimony emphasized, "This works. There is not a problem. There's an easy way to do this." That was his testimony. And that comes from someone——

Dr. McCLELLAN. Right.

Senator DORGAN.—involved in it. And, you know, I think if you had given us the least bit of hope, in the last year and a half, that you were going to do anything other than actively fight this every step of the way, and, in fact, raise issues that I think are specious issues, in a way that scares people, then I—you probably wouldn't be here at this hearing. This is not my preferred way to spend the morning; nor is it perhaps yours. But you've brought this hearing on yourself, in my judgment, and I—you know, look, you, by now, understand, I think, perhaps listening to Senator Lott this morning—Senator Lott is not alone. Day after day after day, those of us, including Senator McCain and others who have been involved in this, understand our colleagues are saying, look, there needs to be an opportunity for open trade in a way that provides safety and deals with safety issues, but there needs to be a way that gives the

American people the opportunity to purchase prescription drugs at a fair price, and that is not the case today, in all too many circumstances.

So, you know I have—I had a whole list of questions, and I think that—I think you understand, from this hearing, a couple of things—at least I hope you do, and I hope you will tell your spokesperson to zip it. It's not about politics; it's about policy. And when you're asked to testify before Committees, you need to respond. Otherwise—the Congress is not going to put in place people that say, “Well, take a hike,” when you're asked to testify.

And I especially point back to Governors summit. These are Republican and Democratic Governors, who came to this town. They're all very concerned about this. They're not interested in doing something that's unsafe for their consumers. They wanted to have a forum, and they invited your agency, and you said no, and yet you sent someone from your agency to another forum down the street that was sympathetic to your point of view that there ought not be reimportation. That's what persuades many of us that there has not been a genuine interest in wanting to work with us.

It is—you know, the fact is that it's reasonable for us to disagree about policy. I'm not—I don't mean to be unfriendly to you. I don't even know you. You know, I mean, we're not—we don't have dinner together, we don't exchange Christmas cards. You, by all accounts, have a great resume, and I'm sure you do wonderful work in a number of areas. But in this area, which is of great concern, to a lot of senior citizens, especially, but all consumers who suffer health problems and simply can't afford prescription drugs, this issue is important. And I've said it many times, miracle drugs offer no miracles to those that can't afford them. And there are too few people here in this 40 or 50 square miles that don't understand the inability to afford prescription drugs you need to save your life.

And so, thank you for being here, and I hope that this discussion is instructive to you, and to the FDA especially.

Dr. MCCLELLAN. Mr. Chairman, do you mind if I take a minute to respond? I want to thank you, Senator, for giving me the opportunity to listen to these concerns. And I appreciate everything that you've said. While we may not agree on each and every policy issue, I actually saw a lot of similarity of views in this room today about the need to find a way to do importation that addresses the safety concerns. And I think there is a consensus that it's going to take legislation to do that, to give FDA some new authorities and new resources to do it.

I will try, as my part in the task force—and I know Secretary Thompson wants to, as well—to move the task force along as quickly as possible to fulfill this mandate from Congress to find the right way to do it. But I also understand that some of the Members, including you, want to address this issue very quickly. And, in the meantime, while our task force is working, we'll try to do it as quickly as possible, we are going to be happy to provide technical assistance to those Members who feel strongly about this issue, and work on legislation.

We may not agree on all the policy issues, but I agree with you that we should provide the technical support, and we should ac-

tively and fully engage on the issue of finding a way to do this safely and effectively.

The CHAIRMAN. Senator Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman.

Dr. McClellan, back to this point about PBMs.

Dr. MCCLELLAN. Yes.

Senator CANTWELL. Because I really think that this legislation that was passed is really playing a very cruel trick on seniors across America. You are telling them that the free marketplace is somehow going to produce this competition that is going to lower the drug prices. And I have to tell you, I had probably 15 to 20 town meetings in January and previously—right when the legislation was passed. Nobody there was buying it. They believe that Medicare should have had a comprehensive plan and negotiated as a big market buyer—

Dr. MCCLELLAN. Yes.

Senator CANTWELL.—and negotiated those prices themselves. But that's not what we're stuck with. And so now the question becomes—and my read of this legislation that was passed does require some audits, does require some disclosures by the prescription drug plans, but it does not require PBMs to disclose. In fact, the Inspector General for the HHS has already tried to get PBMs to disclose this information. That's why some of these attorney generals across the country, and the U.S. Attorney in Pennsylvania, is having challenges with these cases, because they can't get access to the information.

So now here you are, going to be sitting at the top of this big operation in which, underneath you, these discounts and kickbacks are going to be moving back and forth. And the question is, what do you believe should be disclosed? In fact, the Inspector General from the Department of Health even said—or warned that rebates collected by benefit managers working for Medicare programs might violate anti-kickback laws at the Federal level unless amounts paid to companies are disclosed in writing.

So we really don't have this clear today. We don't have clear what has to be reported and by whom. And we're going to hide behind this legislation, saying, "Well, don't worry about that language saying that you don't have to—there's no negotiation on prices. The free market's going to do it." But then you take all the, you know, hands off on making sure that the free market really works with transparency.

So I want to go back again—and I'm happy to hear your reading of this legislation, on closer review—but I want to understand from you, today, whether you think that PBMs should be forced to disclose, to the Attorney General, these rebates, the specific rebates.

Dr. MCCLELLAN. If that's what it takes to assure that beneficiaries are getting lower prices and are getting the benefits that are supposed to come from competition, I think that's something I would support. As I understand it, the Secretary does have some authorities to compel the information that he thinks is necessary to understand whether seniors are really benefiting, under the law, by lower prices.

And I don't mean to put this off. All I meant, with my earlier answer about talking about the regulations that are going to be

forthcoming and so forth, is that I intend to have a full and frank public discussion about the best way to get low prices to seniors under this legislation. And we will put out a proposed rule that will discuss things like what kind of information will be provided to the Secretary to understand what kind of rebates are occurring and whether they're being passed on to seniors, and what kind of information will be provided to seniors to help them understand whether they're getting the best deal or not. And I absolutely welcome your ideas and your thoughts on how we can make sure that seniors are really getting those benefits.

There's one area where I fully agree with you is that if these reductions in prices and reductions in costs don't materialize, seniors and the American public are not going to be satisfied, and they shouldn't be satisfied, and we're going to have to go back and find a different way to do this.

But I do feel like there is a lot that can be done under this current law to get prices down, and I hope we get a chance to work together to do that.

Senator CANTWELL. Well, I don't know if I agree that there's a lot under this current law, but I will take you at your word in saying that you support the rebates if that is what is necessary, because I think that is what's going to be necessary. And so I hope you didn't take your own words lightly, because that is exactly what is needed here. And so I'm going to take those remarks as someone who is serious about making sure that these PBMs disclose rebates. Is that correct?

Dr. McCLELLAN. And I will look——

Senator CANTWELL. Is that——

Dr. McCLELLAN.—forward to working——

Senator CANTWELL.—is that correct?

Dr. McCLELLAN.—with you.

Senator CANTWELL. Is that a correct——

Dr. McCLELLAN. If that's what's necessary to get the low prices to seniors and make sure they're benefiting from the discounts and rebates. And I'm going to look forward to working with you, if I get confirmed, on——

Senator CANTWELL. And what—do we have to disprove if it's necessary? What else do we have to do to prove if it's necessary?

Dr. McCLELLAN. Well, I think one thing to do would be to look at the proposed regulations that the Administration puts out in implementing the Medicare law, and that's going to include a lot of provisions that are going to be designed to make sure that any rebates or discounts that occur are directed to the benefit of seniors. And so we're going to have a chance then to talk about whether the mechanisms are adequate. And we're going to have a chance then to discuss whether further regulatory changes, or maybe even legislation, is necessary to help make sure seniors get the benefits necessary. I'm absolutely committed to working with you in that process.

Senator CANTWELL. Well, I think you have a big task ahead of you——

Dr. McCLELLAN. Yes.

Senator CANTWELL.—in this regard, and I think that—I'm not quite sure you understand the fine line that you're walking here with your testimony.

But thank you, Mr. Chairman.

Dr. McCLELLAN. Thank you, Senator. And I'd be happy to talk with you or your staff further about this to make sure we're doing all we can to address this very important concern.

The CHAIRMAN. Thank you, Dr. McClellan.

I'm a politician, and I think I have a fair idea about public opinion. American public opinion right now, particularly amongst our seniors, is that they want to be able to get their prescription drugs at the lowest possible price. Right now, they see that in Canada and overseas. Despite the power of the pharmaceutical companies, we will pass, as the House has passed, twice now, a requirement for the ability to reimport drugs from Canada. And I believe that will be expanded to other European countries.

So my suggestion is that you prepare for it and be part of the solution, rather than, as is the perception here, that you and the Administration have been blocking it.

I also believe that the provision prohibiting—particularly since the AARP has come out in favor of repeal—well, they've come out for safe importation; they've also come out for repeal of this provision prohibiting Medicare from negotiating—I suggest that you also prepare for that.

One of the reasons why the significant majority of seniors do not support this bill is because they see the not-so-gentle hand of the pharmaceutical company, and they see their inability to import drugs from Canada, and they don't see any lowering of the prices of prescription drugs for any of them. Now, maybe as the law is implemented, we will see those improvements. But right now, with the seniors around American, you've got a lot to prove, and I hope that we will be able to move forward in that fashion.

I thank you for appearing, and you're certainly welcome to respond.

Dr. McCLELLAN. Mr. Chairman, I want to thank you for your leadership and your clear passion and continued passion on the issue of helping seniors, and, in particular, getting them lower prices for medicines that they need in getting them better medical care.

I've appreciated the opportunity to be here today. I've learned something from this process about the importance of interacting with you and your colleagues as constructively as possible.

I'd like to think that this has been a very constructive interchange, in the sense that there is, I think, a lot of consensus around finding ways to make the fundamental changes in the importation law that might be needed to assure safety and to assure the effectiveness of imports, and recognition that, you know, we've got some dedicated professional staff at the FDA that want to make sure drugs are safe, and we need to augment that with new authorities and new resources if we're going to take on the challenge of these additional kinds of imports.

I can also say that if you do pass legislation to do importation, of course the agency is going to do everything it can to implement that law as effectively as possible. My hope would be that, through

our task force and through any technical assistance that we can provide, that legislation would really address the safety concerns that have been raised, and I think there are some legitimate ones, and hopefully we can find a way forward in a very timely way to address that.

So thank you for your leadership, and thank you for the opportunity and for the time that you've taken to hear from me today about this important, important issue.

The CHAIRMAN. Thank you very much.

This hearing is adjourned.

[Whereupon, at 12:07 p.m., the hearing was adjourned.]

